Listeria monocytogenes Workshop

Fall 2003

Food Safety and Inspection Service

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Introduction to the Control of *Listeria monocytogenes* in Ready-to-Eat Products

Introduction to the Control of
Listeria monocytogenes
in Ready-to-Eat Foods

Introduction to the Control of *Listeria monocytogenes* (*Lm*) in Ready-to-Eat Products; Interim Final Rule

Small and Very Small Establishment Implementation Workshop

1

Control of *Lm* in RTE products

- Background
  - FMIA, PPIA
    - wholesome, not adulterated, and properly marked, labeled, and packaged.
  - FMIA and PPIA: *Adulteration*
    - bears or contains any poisonous or deleterious substance that may render it injurious to health
    - been prepared, packed, or held under insanitary conditions

2

Control of *Lm* in RTE products

- **Background:**
  - During the 1980's, *Lm* began to emerge as a problem in processed meat and poultry products.
  - In the 1990's, outbreaks of foodborne illness caused by *Lm*.
  - From 1999-2003 various Agency publications were issued addressing *Lm*

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Control of *Lm* in RTE products

- **Background:**
  - Federal Register Interim Final Rule 6/6/2003
    - Control of *Listeria monocytogenes* in RTE Meat and Poultry Products; Final Rule
    - 9 CFR Part 430

4

Control of *Lm* in RTE products

- Implementation of new RTE regulations
  - Why do I need to make changes?
  - How does this affect establishments producing RTE products?
  - What are the changes or new requirements?
  - When will I be required to make the change?
  - Will I need to modify my SSOP and/or HACCP plan?

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§430.4 Control of Lm in Post-lethality Exposed RTE Products

- *Lm* can contaminate RTE products that are exposed to the environment after a lethality treatment (destroy/kill).
- *Lm* is a hazard that an establishment must control through its HACCP plan, or prevent in the environment through a SSOP or other prerequisite program if it produces RTE product that is exposed post-lethality.
- RTE product is adulterated if it contains *Lm* or if it contacts surfaces contaminated with *Lm*.

6

Control of Lm in Post-lethality Exposed RTE Products

- In order to maintain sanitary conditions necessary to meet this requirement, an establishment producing post-lethality exposed RTE product must comply with one of three alternatives.

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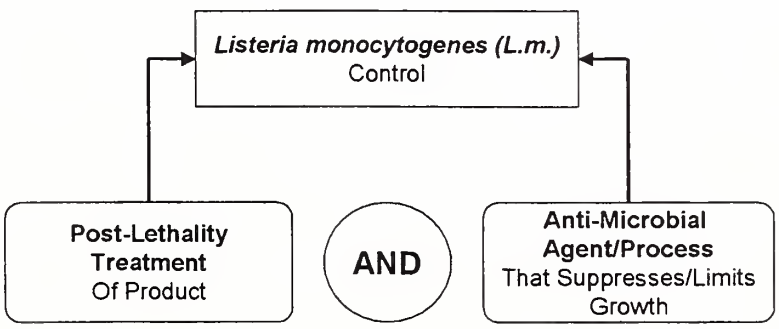
Alternative 1



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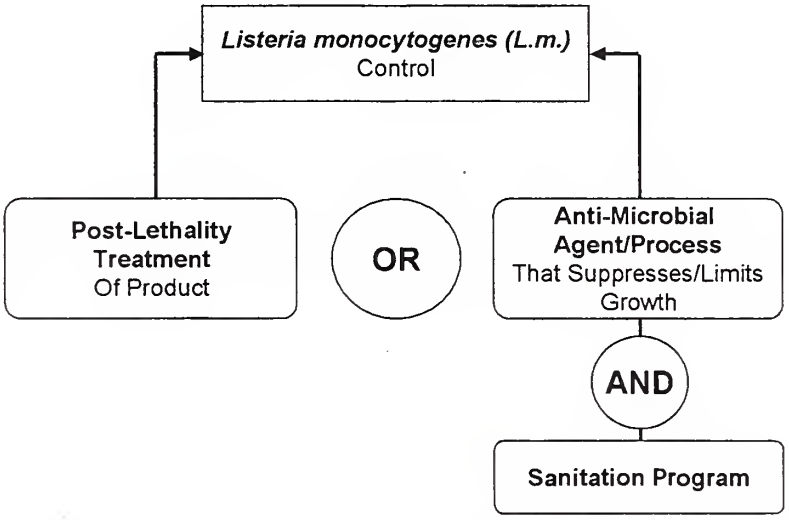
Alternative 2



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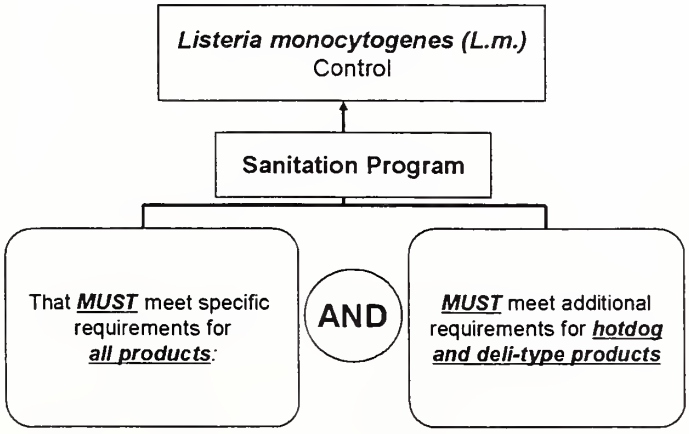
Alternative 3



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Risk to Product

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For All Three Alternatives

1) Establishments may use verification testing, which would be in addition to FSIS verification testing, that includes tests for *Lm* or an indicator organism, such as *Listeria* species, to verify the effectiveness of their sanitation procedures in the post-lethality processing environment.

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For All Three Alternatives (cont.)

2) Sanitation measures and procedures for antimicrobial agents or processes that control *Lm* may be incorporated either in the establishment's HACCP plan or in its SSOP or other prerequisite programs. If these control procedures are included in the SSOP or prerequisite program, and not as a CCP in the HACCP plan, the establishment must have documentation supporting the decision in its hazard analysis that *Lm* is not a hazard reasonably likely to occur.

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For All Three Alternatives (cont.)

3) Establishments must maintain sanitation in the post-lethality environment in accordance with part 416.
4) If *Lm* control measures are included in the HACCP plan, the establishment must validate and verify the effectiveness of these *Lm* control measures in accordance with § 417.4.

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For All Three Alternatives (cont.)

5) If *Lm* control measures are included in the SSOP, the effectiveness of these measures must be evaluated in accordance with § 416.14.
6) If the *Lm* control measures are included in a prerequisite program other than the SSOP, the program and the results produced by the program must be included in the documentation that establishment is required to maintain in accordance with § 417.5.

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For All Three Alternatives (cont.)

7) The establishment must make the verification results that demonstrate the effectiveness of the *Lm* control measures it employs, whether under its HACCP plan or SSOP or other prerequisite program(s), available to FSIS inspection personnel upon request.

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Supplying Information to FSIS

An establishment that produced post-lethality exposed RTE product shall provide FSIS, at least annually, or more often as determined by the Administrator, with estimates of annual production volume and related information for the types of meat and poultry products processed under each alternative specified in § 430.4(b).

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Labeling Claims

Establishments that control *Lm* by using a post-lethality treatment or an antimicrobial agent or process that eliminates or reduces, or suppresses or limits the growth of *Lm*, may declare this fact on the product label provided that the establishment has validated the claim.

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Workshop
Breakout sessions

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Ready-to-Eat Labeling Identification and Product Categories

Ready-to-Eat
Labeling Identification
and Product Design

WORKSHOP 1

The New *Listeria Regulation*

IS THE REGULATION APPLICABLE TO YOUR PRODUCT?

Labeling, Identification, and Post-Lethality Control Alternatives

1

IS THE REGULATION APPLICABLE TO YOUR PRODUCT AND WHAT IS THE APPROPRIATE POST-LETHALITY CONTROL ALTERNATIVE ?

- Step 1
  - Determine whether the product is a Ready-to-Eat (RTE) product
- Step 2
  - Determine whether the RTE product is exposed post-lethality
- Step 3
  - Determine whether the product is a deli or hotdog product
- Step 4
  - Determine the control measures used for the product and the alternative into which your product fits

2

Step 1

Determine Whether the Product is RTE

3

Is the Regulation Applicable to My Product?

- Step 1
  - Determine whether the product is a Ready-to-Eat (RTE) product
    - Some products are defined by standards as RTE
    - Some products expected to be RTE
    - Some products may be RTE or may be not-ready-to-eat (NRTE)
    - Some products are labeled to represent them as RTE

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- Step 1 Continued

Definition of Ready-to-Eat (RTE) Product
(9 CFR 430)

- A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety
- May receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes
- Can include frozen meat and poultry products

5

Other Regulatory Terms Defined in the Lm Rule

- Antimicrobial Agent
- Antimicrobial Process
- Deli Product
- Hotdog Product
- Lethality Treatment
- Post-lethality Processing Environment
- Post-lethality Treatment

6

Step 1 Continued

Examples of RTE Products
Five Categories That May Represent RTE Products But That May or May Not Be Post-Lethality Exposed

- Cooked or Otherwise Processed Whole or Comminuted Products
- Fermented Meat and Poultry Products
- Salt-cured Products
- Dried Products
- Thermally-Processed, Commercially Sterile Products

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Step 1 Continued

-- Cooked or Otherwise Processed Whole or Comminuted Products

Includes Meat and Poultry Products Such As These, or Containing These:

- Cooked/cured sausages, e.g., bologna, hotdogs, weiners, turkey franks, cotto salami, poultry roll
- *Cooked/smoked sausages, e.g., berliner, cheese smokies*
- Cooked sausages, e.g., pork sausage patties, brown and serve sausages
- *Cooked pastrami, corned beef, roast beef, roast pork, cooked ham, fried chicken, cooked/breaded chicken nuggets*

8

Step 1 Continued

-- Cooked or Otherwise Processed Whole or Comminuted Products

Includes Meat and Poultry Products Such As These, or Containing These:

- Meat or poultry loaf, gyros
- *Cooked meat or poultry chili, stew, ravioli*
- Cooked pork in BBQ sauce, chicken/turkey BBQ
- *Chicken burritos, pork eggrolls*
- Entrees/dinners

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Step 1 Continued

-- Fermented Meat and Poultry Products

Includes Meat and Poultry Products Such As These, or Containing These:

Lebanon bologna
Pepperoni
Cervelat
Chorizo
Genoa or Italian salami
Summer sausage
Cacciatore (a dry sausage)

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Step 1 Continued

-- Salt-cured Products

Includes Meat and Poultry Products Such As These, or Containing These:

Coppa
Country ham
Parma ham
Prosciutto
Dry cured duck

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Step 1 Continued

-- Dried Products

Includes Meat and Poultry Products Such As These, or Containing These:

Beef sticks
Meat/poultry jerky
Basturma, Pastirma
Dried beef

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- **Step 1 Continued**

-- Thermally-Processed, Commercially Sterile Products

Includes Meat and Poultry Products Such As These, or Containing These:

Canned ham

Canned soups with meat or poultry

Canned meat/poultry stew, ravioli, lasagna

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- **Step 1 Continued**

-- Identifying a RTE Product

- RTE products are not required to bear safe-handling instructions (as required for non-RTE products by 9 CFR 317.2 (k)(1) and 381.125(b)
- RTE product labeling does not instruct the consumer that the product must be cooked or otherwise treated for safety
- In many cases, RTE product labeling is guided by various factors .....

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Step One Continued
Identifying a RTE product

1. By standard of identity in regulations or policy in Food Standards and Labeling Policy Book

e.g., hotdogs are defined as "cooked" products

8 Skinless Beef Franks

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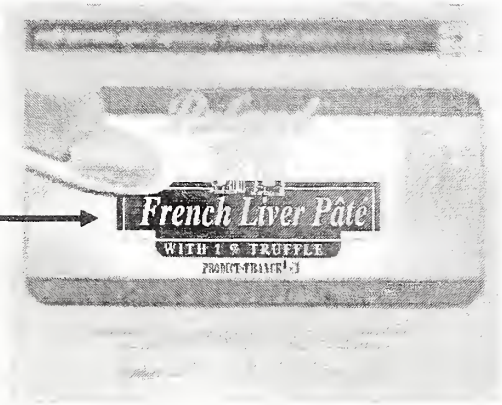
Identifying a RTE product

2. Consumer expectations/long term production practices

e.g., Pates – understood by consumers to be a RTE product



French Liver Pate with 1% Truffle

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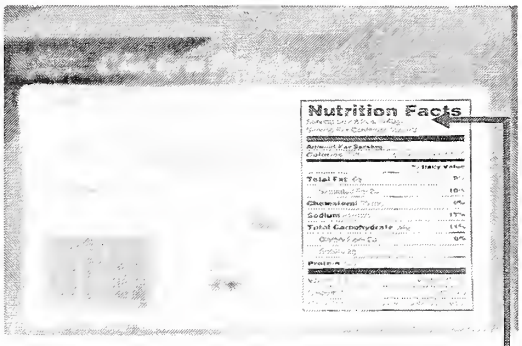
Identifying a RTE product

3. Nutrition Labeling- Serving size for RTE products are based on ready-to-serve reference amounts

   Reference Amounts Customarily Consumed (RACC)

   – Potstickers ready to serve = 140 grams (g)



Serving Size 8 Pcs. (140g)

17

Identifying a RTE product

4. Labeling terms on principal display panel (PDP) of product labels

   Examples:

   – Heat and serve
   – Ready to eat

Simply heat and serve

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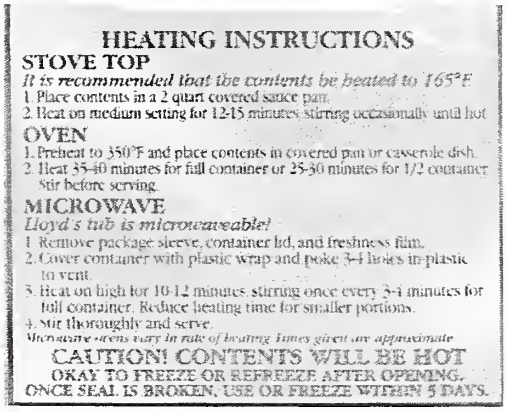
Identifying a RTE product

5. Preparation Instructions

Examples:

- Microwave Oven Preparation
- Conventional Oven Preparation



HEATING INSTRUCTIONS

STOVE TOP

It is recommended that the contents be heated to 165°F

1. Place contents in a 2 quart covered sauce pan.
2. Heat on medium setting for 12-15 minutes stirring occasionally until hot

OVEN

1. Preheat to 350°F and place contents in covered pan or casserole dish.
2. Heat 35-40 minutes for full container or 25-30 minutes for 1/2 container.
   Stir before serving.

MICROWAVE

Lloyd's tub is microwaveable!

1. Remove package sleeve, container lid, and freshness film.
2. Cover container with plastic wrap and poke 3-4 holes in plastic to vent.
3. Heat on high for 10-12 minutes stirring once every 3-4 minutes for full container. Reduce heating time for smaller portions.
4. Stir thoroughly and serve.

Microwave ovens vary in rate of heating. Times given are approximate

CAUTION! CONTENTS WILL BE HOT

OKAY TO FREEZE OR REFREEZE AFTER OPENING.
ONCE SEAL IS BROKEN, USE OR FREEZE WITHIN 5 DAYS.

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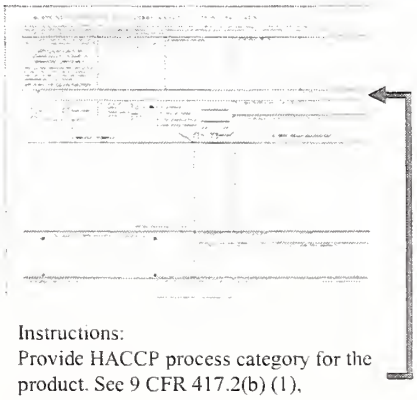
Identifying a RTE product

6. HACCP category

i.e., HACCP category – is entered into block 5B on the FSIS Form 7234-1 (10/03/2002)

Examples

- Not heat treated-shelf stable
- Heat treated- shelf stable
- Fully cooked – not shelf stable



Instructions:
Provide HACCP process category for the product. See 9 CFR 417.2(b) (1),

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Step 2

Determine Whether the RTE Product Is Post-Lethality Exposed

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Step 2 Continued -- Determine Whether the Product Is Post-Lethality Exposed

- Post-Lethality Exposure
- Is there direct exposure of RTE product to a food contact surface or the processing environment after the lethality treatment?
- Examples of routes of exposure to food contact surface in processing environment
  - slicing
  - peeling
  - re-bagging
  - cooling semi-permeable encased product with brine solution

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Step 2 Continued -- Determine Whether the RTE Product Is Post-Lethality Exposed

Environmental-type Routes of Contamination

- Direct Contact
  - -- Direct exposure of RTE product to a food contact surface
- Indirect Contact
  - -- Potential contact of exposed RTE product
    - Handling a mop handle with a hand and then touching RTE product
    - Soiled apron touching product
- No Contact
  - -- Floors, drains, overhead structures

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Step 3

Determine Whether the Product Is a Deli or Hotdog Product

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Step 3 Continued
Is My Product a Deli or Hotdog Product?

- Now that you know which of your products is applicable to the new *Listeria* rule (i.e., post-lethality exposed RTE), determine whether your product is a **deli** or **hotdog** product, as defined in the rule

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Deli and Hotdog Products

- Deli products are RTE meat or poultry products that are typically sliced, either in an official establishment or after distribution from establishment, and typically assembled in a sandwich for consumption, e.g., spiral cut bone-in hams; bologna; boiled/baked ham; roast beef; turkey breast; chicken roll

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Deli and Hotdog Products

- Typical hotdogs are RTE meat or poultry franks, frankfurters, weiners per 9 CFR 319.180 standard (thus, does not include products like bratwurst, polish sausage, other cooked sausages covered by 9 CFR 319.140)

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Step 4

Determine the Control Measures Used for the Product

and

the Alternative Into Which Your Product Fits

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Step 4
Into Which Alternative Does My Product Fit?

- Now that you know which of your products are covered by the new *Listeria* rule (i.e., post-lethality exposed RTE), determine which alternative control measure your product fits into.

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Step 4 Continued
Into Which Alternative Does My Product Fit?

- Alternative 1 Product
  - -- Post-lethality treatment **and** antimicrobial agent/process
  - -- The Post-lethality treatment and antimicrobial agent/process must each be documented to be sufficient to provide enhanced safety.

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Step 4 Continued
Into Which Alternative Does My Product Fit?

- Alternative 2 Product
  - -- Post-lethality treatment **or** antimicrobial agent/process
  - -- The Post-lethality treatment **or** antimicrobial agent/process must be documented to be sufficient to provide enhanced safety.

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Step 4 Continued
Into Which Alternative Does My Product Fit?

- Alternative 3 Product
  - -- Use of sanitation measures only (in accordance with 9 CFR 430.4 (b)(3)
    - * May have post-lethality treatment and/or antimicrobial agent/process but not documented as being sufficient to provide enhanced safety
  - -- Special restrictions regarding potential adulteration of deli and hotdog products

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Labeling of RTE Products

- **Ingredients Statements**
- **Claims Based on Use of Antimicrobial Ingredients and Post-Lethality Treatments**

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Labeling Ingredients in Formulations of RTE products

e.g., Hotdog Ingredients: pork, water, beef, dextrose, salt, corn syrup, **sodium lactate,** flavorings (spice extractives, garlic powder), modified food starch, sodium phosphate, **sodium diacetate**, paprika, sodium erythorbate, sodium nitrite.

- Modifying an ingredients statement to add a safe and suitable antimicrobial agent may be done generically

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Labeling of RTE Products for Post-Lethality Treatment and Antimicrobial Claims

- Labels for RTE products that bear claims about antimicrobial agents in formulations and post lethality treatments **must** be submitted to Labeling and Consumer Protection Staff (LCPS) for review
- Examples of claims:
  - Contains sodium diacetate and sodium lactate to prevent the growth of *Listeria monocytogenes*.

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Label Claims for Enhanced Safety

- Labeling claims about the enhanced safety of a product (regarding Listeria) are more likely to be approved if the post-lethality treatment achieves a 1 log reduction or greater of *L. monocytogenes,* and if the antimicrobial agent or process suppresses *L. monocytogenes* growth such that there is 1.0 log or less increase throughout the product's expected shelf-life

  ** unless compelling supporting data are provided to address less rigorous lethality/growth parameters

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Distinguishing RTE From Not Ready-to-Eat (NRTE) Products by Labeling

Guidance provided in Attachment 2, FSIS Directive 10,240.3 (12/09/2002)

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The End

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Sanitation
Alternative 3

Sanitation

Alternative 3

1

How does *Lm* get into plants and RTE food products?

- Because *Lm* is everywhere in the environment it can easily enter the processing plants (transported by humans, equipment, vehicles, shoes, etc.)
- Once inside a processing plant (typically cold and wet environment), *Lm* can establish itself and persist for long periods of time

2

FSIS *Listeria* Risk Assessment

- *Listeria* positive food contact surfaces result in increased likelihood of RTE products positive for *Lm.*
- Combinations of interventions were shown more effective at reducing potential contamination of RTE products with *Lm* than a single intervention

3

Post-Lethality Environment

- *Lm* can continually be re-introduced into the plant environment
- When present in the plant environment *Lm* can eventually lead to contamination of food contact surfaces and RTE product

4

Why have Testing in your Sanitation Program?

- *Required* for plants that choose Alternative 3
- *Required* for plants that choose Alternative 2 and choose to use only an antimicrobial agent or process that suppresses or limits the growth of *Lm*
- Verify sanitary condition(s)
  - Essential to continually assess a plant's *Lm* controls
  - Identify problems and *Lm* contamination sources that would otherwise go undetected

5

Alternative 3 (and 2)

- Establishment sanitation program must:

A. Test food contact surfaces in post-lethality processing environment
B. Identify the conditions to start hold-and-test procedures following positive test of food-contact surface for *Lm* or indicator organism
C. State testing frequency
D. Identify size and location of sample sites
E. Explain why testing frequency is sufficient to ensure effective control of *Lm* or indicator organisms

6

Alternative 3 only

- Deli product or hotdog product additionally:

  A. Verify corrective action after positive test of a post-lethality contact surface
     - Follow-up testing to ensure effectiveness
  B. If follow-up testing results in a second positive, establishment must hold lots until corrected
  C. Sample and test with statistical confidence level before product can enter into commerce or rework held product

7

Harborage Site or Niches

- The location in the food processing environment where microorganisms can live and multiply.
- A place where they can hide, spread, and contaminate equipment/product.
- Niches may contain spoilage organisms and/or pathogens.
- Microbiological testing is necessary to detect the niche.

8

Biofilm

- A bacterial film that is attached to a surface and protects the organism.
- Biofilms make sanitizers less effective.
- Biofilms can occur on surfaces such as metal, flooring materials, rubber, fabric, wood that are infrequently or inadequately cleaned.

9

Testing Program

- Food Contact
  - Equipment
  - Workers
  - Packaging
- Non-Food Contact Surfaces
  - Environment
- Other Factors

10

Sanitation

Workshop Discussion

Refer to Handout

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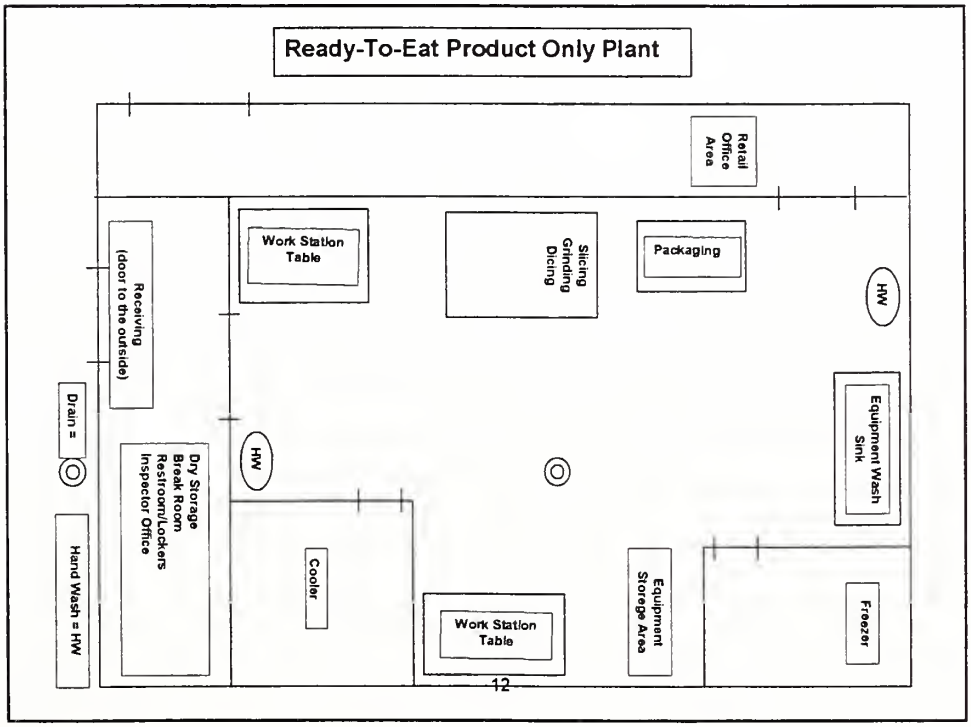

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Color Codes

- GREEN = People traffic pattern
- BLUE = RTE Product flow
- ORANGE = Raw Product flow
- PINK = Inedible / Trash flow
- RED = Food Contact Sampling Sites
- TAN = NON CONTACT Environmental Sampling Sites

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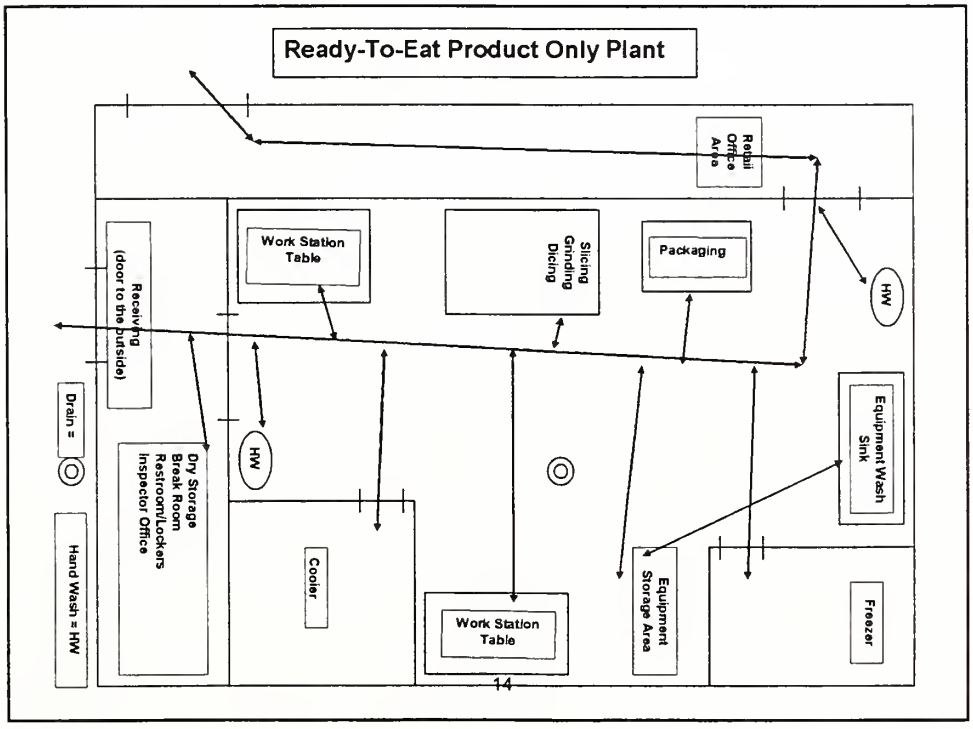

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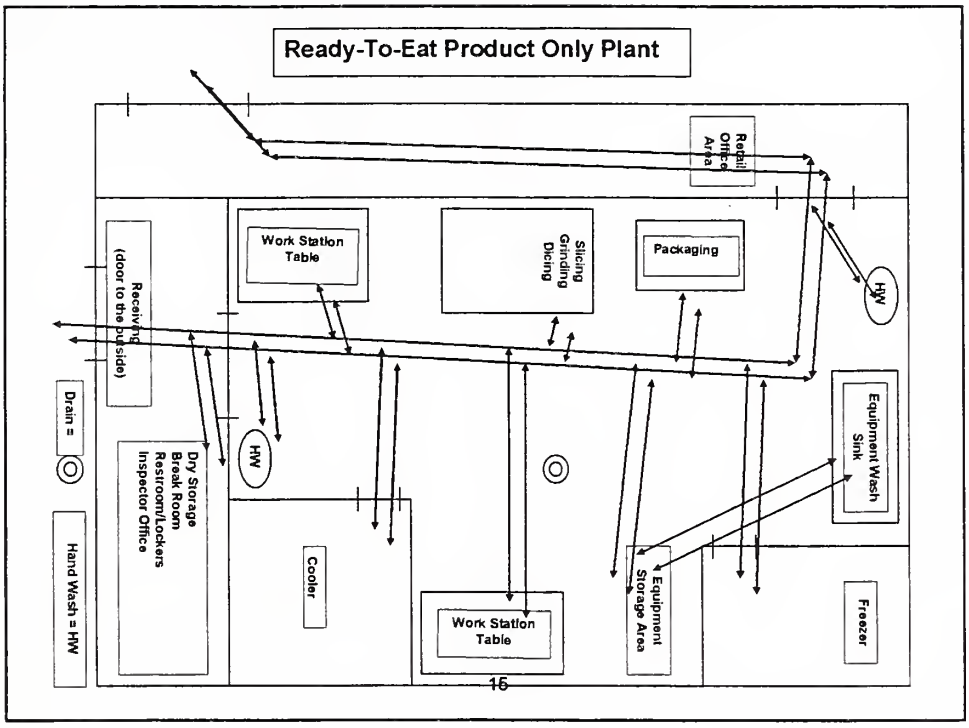
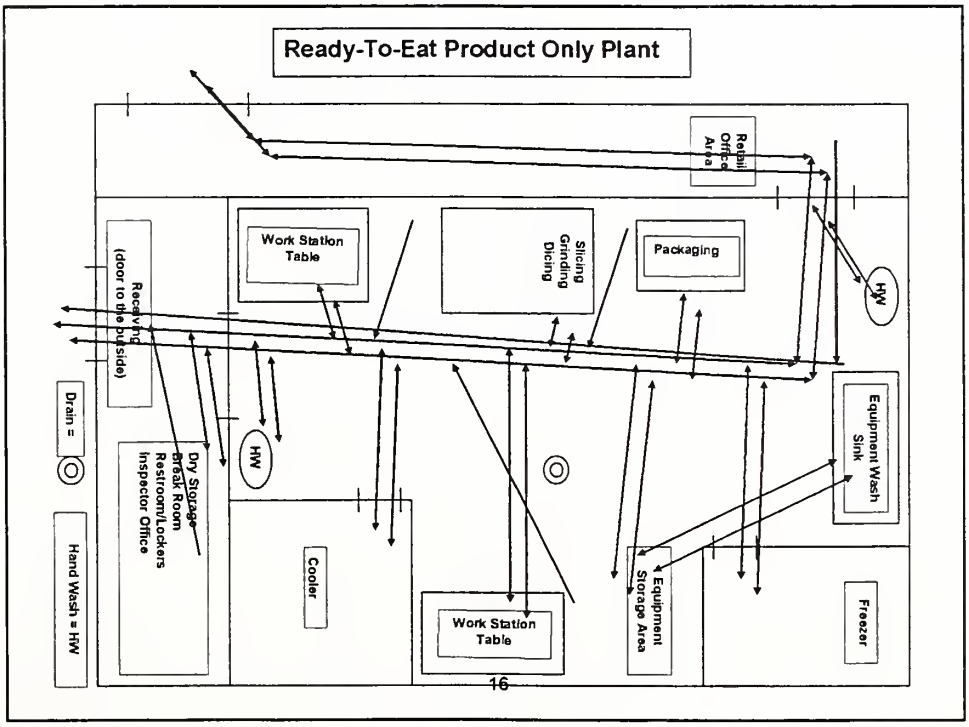

Ready-To-Eat Product Only Plant
Retail Office Area
Work Station Table
Slicing Grinding Dicing
Packaging
HW
Receiving (door to the outside)
Equipment Wash Sink
Drain =
Dry Storage Break Room Restroom/Lockers Inspector Office
HW
Cooler
Work Station Table
Equipment Storage Area
Freezer
Hand Wash = HW
15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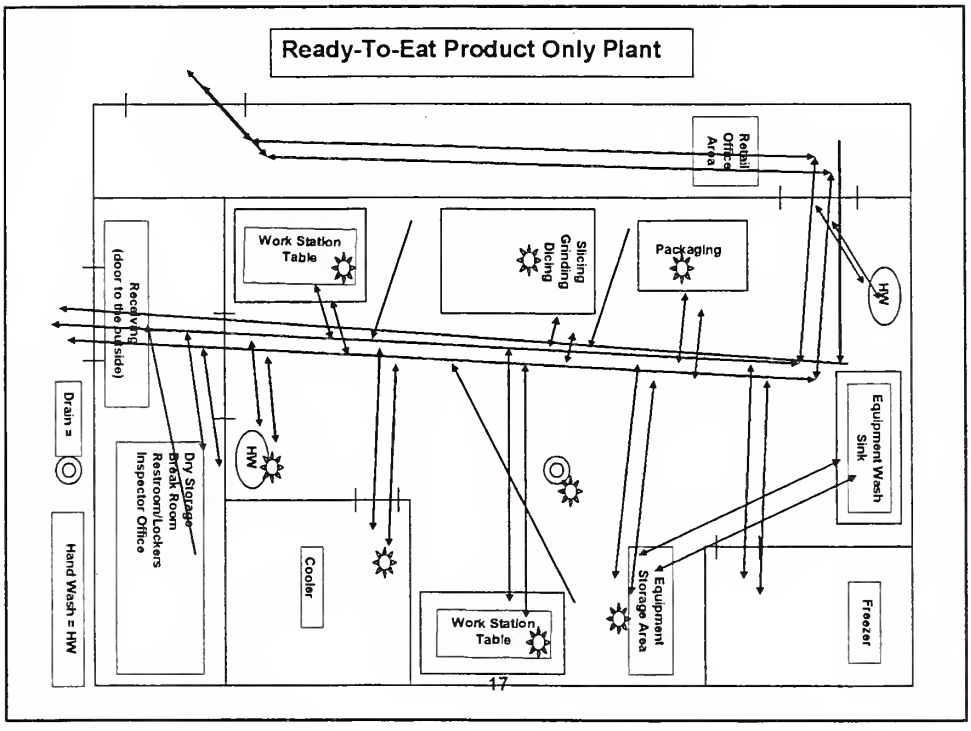
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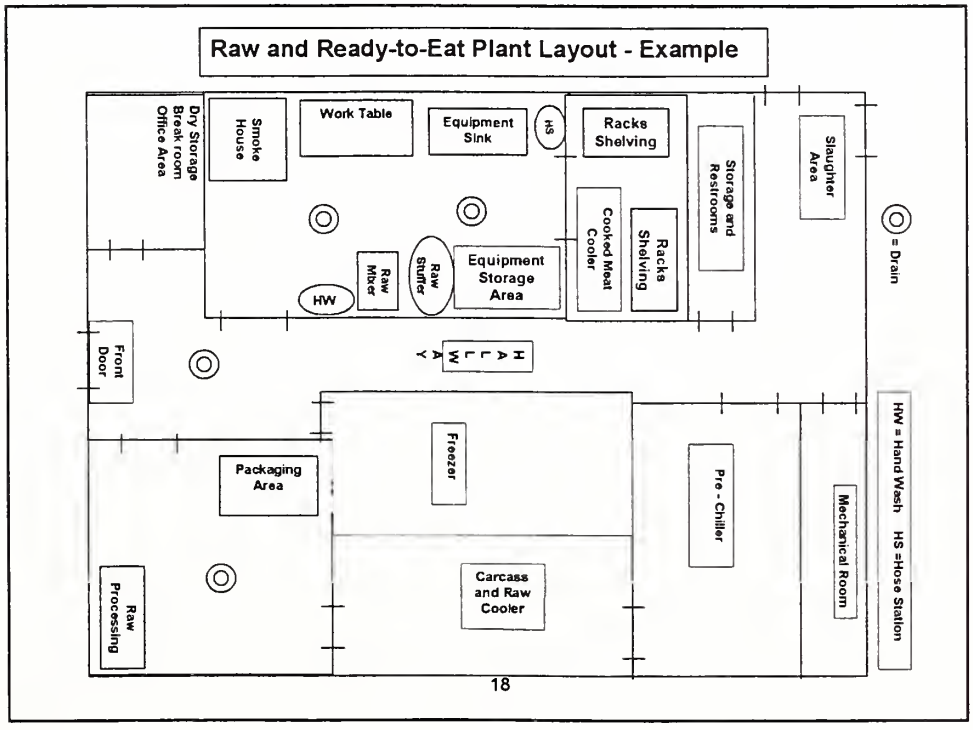
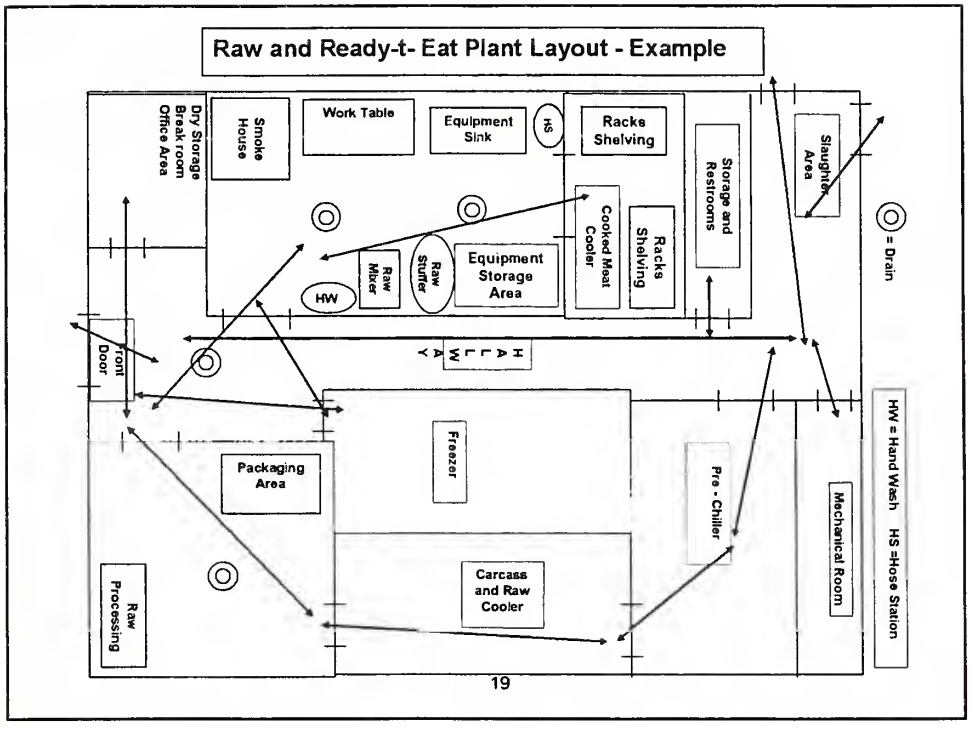

Raw and Ready-to-Eat Plant Layout - Example
Dry Storage Break room Office Area
Smoke House
Work Table
Equipment Sink
HS
Racks Shelving
Storage and Restrooms
Slaughter Area
= Drain
Cooked Meat Cooler
Racks Shelving
Raw Mixer
Raw Stuffer
Equipment Storage Area
HW
HAND WASH
Front Door
Packaging Area
Freezer
Pre - Chiller
Mechanical Room
HW = Hand Wash HS =Hose Station
Carcass and Raw Cooler
Raw Processing
18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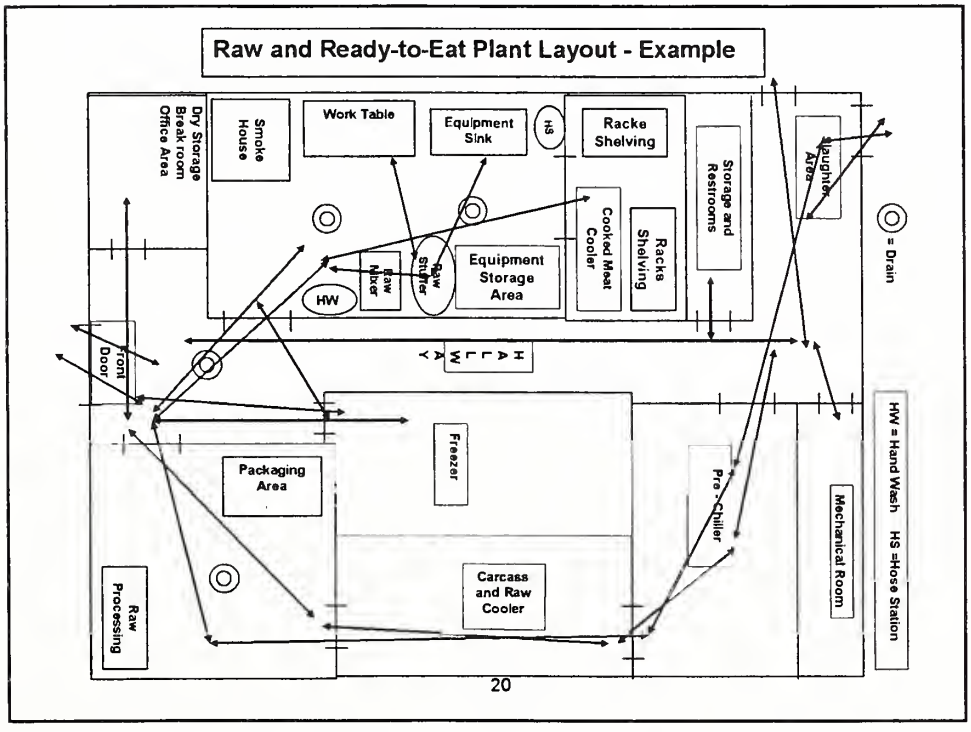
HW = Hand Wash HS =Hose Station
19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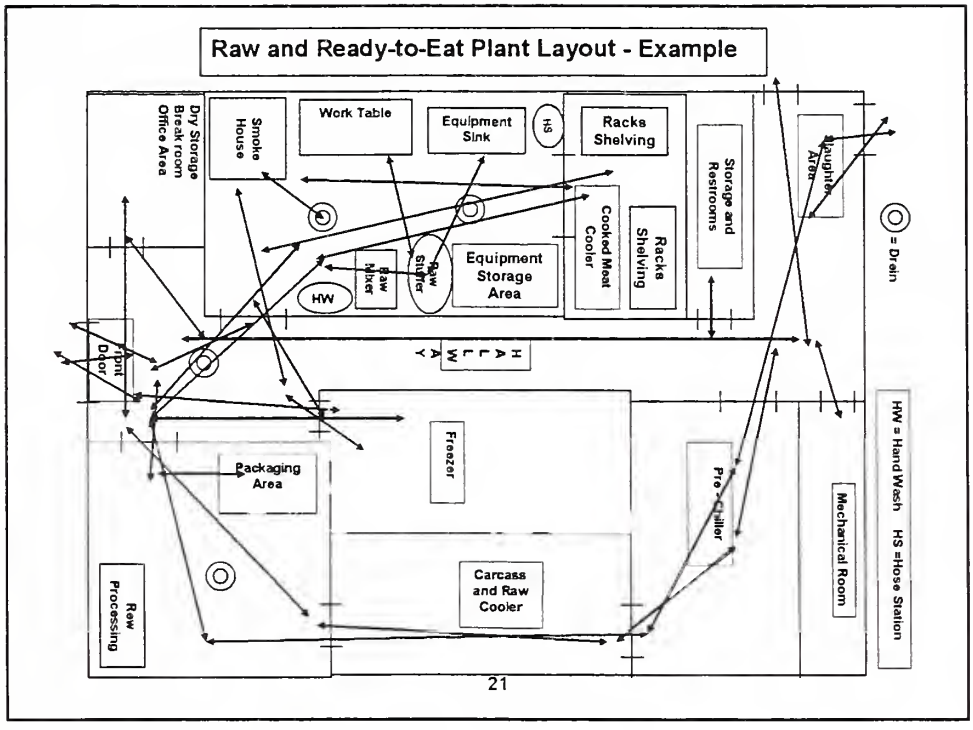
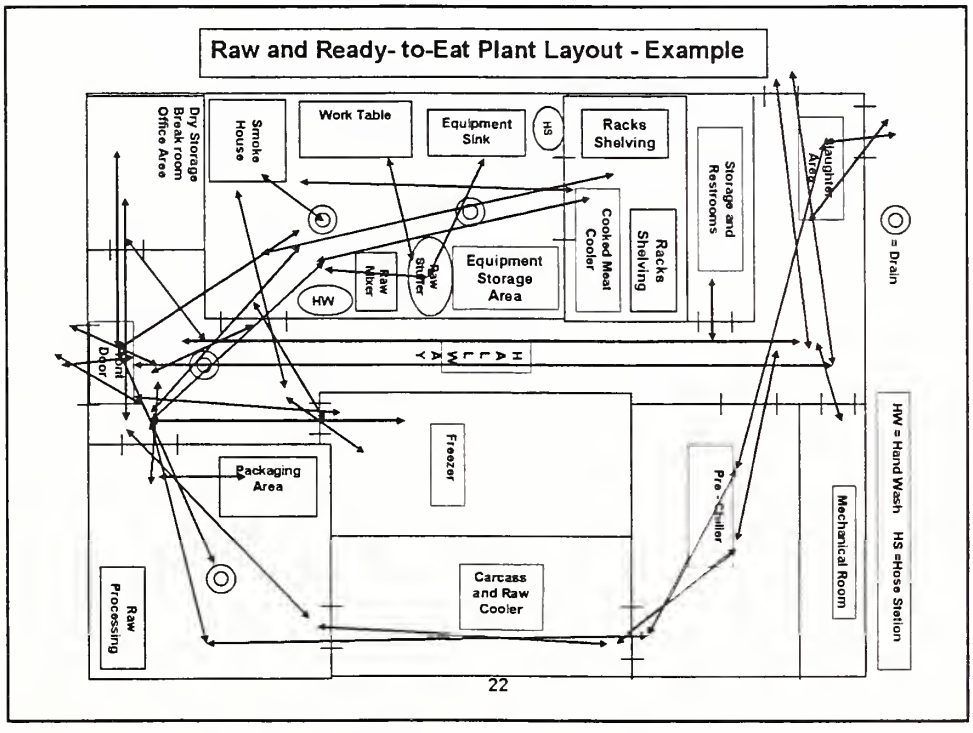
Carcass and Raw Cooler
HW = Hand Wash HS =Hose Station
20


Raw and Ready-to-Eat Plant Layout - Example
Dry Storage
Break room
Office Area
Smoke House
Work Table
Equipment Sink
HS
Racks Shelving
Storage and Restrooms
Slaughter Area
= Drain
Cooked Meat Cooler
Racks Shelving
Raw Mixer
Raw Stuffer
Equipment Storage Area
HW
HALLWAY
Joint Door
Packaging Area
Freezer
Pre - Chiller
Mechanical Room
Carcass and Raw Cooler
Raw Processing
HW = Hand Wash HS =Hose Station
21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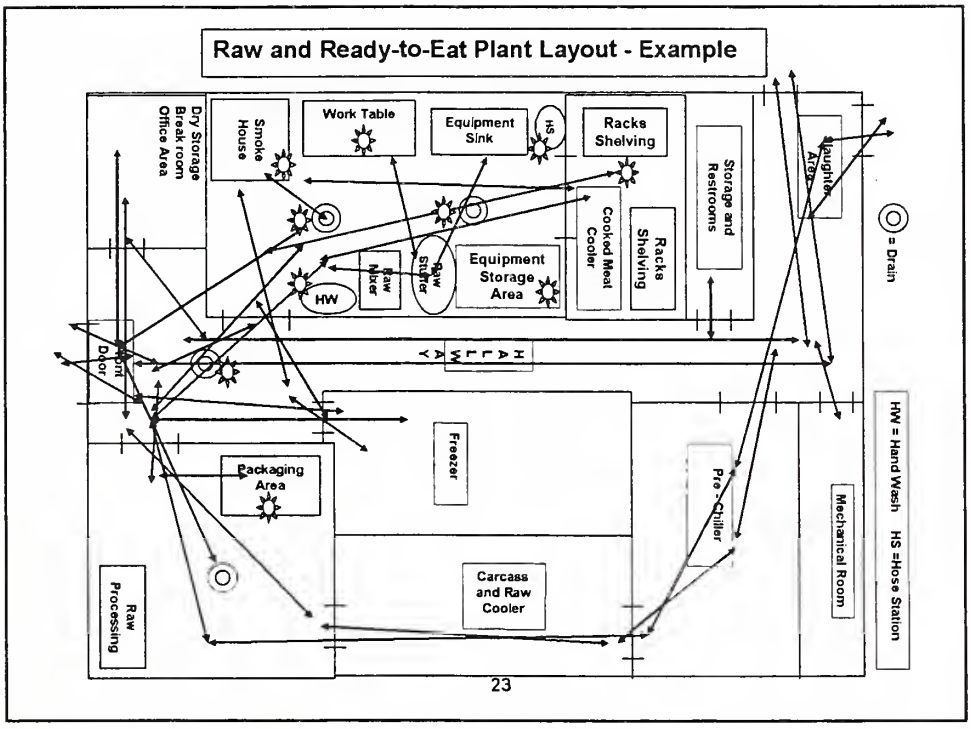

Testing Frequency

- Testing frequency should be based on:
  - History and trends
  - Features of the plant
  - Type of product and volume
  - Plant layout
  - Product flow

24

Materials Needed for Testing

- Surface Testing
  - Pre-sterilized sponges in the sample bag or commercially available kit
  - Sterile sample bags
  - Sterile, disposable gloves
  - Sterile neutralizing broth (e.g., Dey-Engley (D/E))
  - Clipboard

25

Materials Needed for Testing (Cont.)

- Surface Testing
  - A basket to hold the sample bags for preparation
  - Marking pen and label stickers
  - Sample shippers with pre-frozen refrigerant packs and cardboard separator
  - A system for next day delivery to the lab
  - Plastic bags for trash

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Materials Needed for Testing

- Product Testing
  - Product sample in the final, intact package
  - Sterile sample bags
  - A basket to hold the sample bags for preparation
  - Marking pen and label stickers
  - Sample shippers with pre-frozen refrigerant packs and cardboard separator
  - A system for next day delivery to the lab

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Materials Needed for Testing (Cont.)

- Liquid Testing
  - Sterile ladles with handles for aseptic handling of solution
  - Sterile, disposable gloves
  - Sterile plastic specimen cups with water tight screw caps
  - Self-closing bags of an appropriate size
  - Sterile disposable pipettes
  - Pipettor or equivalent

28

Sampling Technique

Workshop Demonstration

29

How to Collect a Sample

- Sampling Procedure Example:
  - Sterile gloves may or may not be required
  - Wash and sanitize your hands
  - Open the bag containing the pre-sterilized sponge
  - Aseptically pour sterile neutralizing broth into bag to hydrate the sponge
  - Press the mouth of the bag back together
  - Moisten the sponge by using hand pressure on outside of the bag

30

How to Collect a Sample (Cont.)

- Sampling Procedure Example
  - Squeeze the excess broth out of the sponge
  - Carefully take the sponge out of the bag
  - Swab at least a 1 foot square area
  - Swab the area vertically ten times, then use other side of sponge to swab horizontally and diagonally, 10 times respectively

31

How to Collect a Sample (Cont.)

- Sampling Procedure Example
  - Open the bag and insert the sponge back into the bag
  - Grip the sponge through the bag
  - Squeeze air out of the bag. Fold the top of the bag down at least 3 times. Fold in the tabs to lock the fold in place

32

How to Collect a Sample (Cont.)

- Sampling Procedure Example
  - The primary container is placed into a self-closing bag with an identifying label. Label with company name, date, time, and location
  - As soon as possible, place the bagged sponge inside an insulated sample shipper

33

Packing the Sample

- The shipping containers should be pre-chilled. Place two pre-frozen gel packs into the bottom of the pre-chilled container.
- Place a cardboard separator on top of the gel packs and then put in the samples.
- Add a foam plug or cardboard
- Send the boxes to the lab by overnight shipment or by other means acceptable to the lab.

34

Participant practice session

Take Home Message:

- **Always maintain aseptic technique**

35

Conclusion

- **FSIS may perform more frequent verification testing if the establishment chooses Alternative 3**

- **Log onto www.fsis.usda.gov**
  - **More Hot Topics**
    - ***Listeria monocytogenes***

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RTE Implementation
Small and Very Small Outreach Program Workshop
Testing Program Considerations
Sanitation Program

Step 1: Identify the risk elements to your processing environment:
What may be the potential sources of *Listeria monocytogenes* (in-plant)? How would it get into my processing environment?

Raw materials and/or ingredients
- Improper Separation of Raw Product Vs. Cooked Product

Employees/Visitors
- Improper Employee Traffic Patterns & Practices

Equipment
- Improper Cleaning of Equipment or improper use of cleaning compounds

Environment

Airflow/Aerosols
- Improper Air Flow Through the Exposed Product Area

Construction/Maintenance

Brine/Water Reuse Programs

What do you think about your establishment? List some risks you might need to focus on or address in your establishment.

Using a blank sheet of paper please draw your ready-to-eat processing environment with the equipment and product flow and adjoining rooms to use as we go through the rest of this workshop to assist you in creating a sanitation program that will work for you and meet the requirements. Remember that each plant will have a unique plan to their specific environment.

Step 2: Let's now think about possible harborage sites in post-lethality food contact surfaces that may be contaminated with *Listeria. monocytogenes*

- Casing peelers
- Shelves and racks
- Lugs, tubs, pans, and containers
- Hand tools, gloves, and aprons
- Packaging materials
- Packaging equipment
- Tables
- Conveyors, belts, and rollers
- Sponges and brushes for cleaning
- Conveyor belts
- Chutes
- Cutting boards
- Slicers (blades, bearings, belts, hoppers)
- Compressed air systems
- Shredders (hooks, belts, bearings, hoppers)
- Saws (blade, wheels, bearings, tables)
- O-rings and O-ring grooves
- Racks
- Dicers

Think about your processing environment? What food contact surfaces do you have? List some.

Step 3: Where else would opportunities exist for contamination from the environment?

- Air or High pressure water hose spray may splash or atomize and carry *Lm* from floors or drains on to tables or equipment.
- Construction (e.g. breaking out walls or other activities that can generate dust)
- Chilling brine (may be lower priority because of dilution)
- Workers
  - Hygiene
  - Personal equipment – gloves, knives, tongs, probes, thermometers, spatulas, hooks, and aprons (if touching product)
- Packaging (may be lower priority due to storage and handling practices, which are important)
  - Film wrap
  - Bags
  - Soaker pads

What other areas can serve as potential reservoirs of *Listeria. monocytogenes?*

- Floors and drains
- Standing water (e.g. condensation drip pans)
- Ceilings and overhead pipes
- Refrigeration condensation units
- Wet insulation (exposed to processing area)
- Cleaning tools (sponges, brushes, squeegees)
- Overhead rails and trolleys
- Maintenance tools (wrenches, screwdrivers)
- Wooden pallets
- Fork lifts/pallet jacks

Other sites where *Listeria monocytogenes may hide include:*

- Any recess or hollow material such as rollers, switch boxes, box cutters, motor housings. What else can you think of in your plant?
- Rusted materials on equipment frames or pipes, cracked or pitted rubber hoses or door seals, walls, floor, or ceilings that are cracked, pitted, or covered with inadequately sealed surface panels shelving. Is your facility or equipment kept in good repair?

Where else should you look or investigate for possible niches or harborage sites?

- Vacuum/air pressure pumps, lines, and hoses
- Ice makers
- Air filters
- Open bearings or bolt threads and exposed threaded connections
- Table edges
- Equipment hanging over products
- Belt rollers
- Vapor exhaust chutes
- Conveyor belt undersides
- Product pan handles/underside
- Implement handles
- Switches, control buttons, levers
- Bottom/side edges of stools/chairs
- Pan/tub hand-hold lips
- Cleaning equipment
- Drains and drain lid undersides
- Hollow beams, legs, rollers, supports
- Water collection spots

- Wall seeps or wet spots on walls, ceilings, wall-floor juncture
- Loading/shipping docks (switches, walls, floors)
- Roofs (puddles, cracks)
- Outside Premises
- Overhead pipes with condensation or dust
- Cooling coil condensate drain pans
- Condensate mops
- Ovens (exterior)
- Room switches
- Telephones and key pads
- Door handles and door pulls
- Air handlers/fans
- Evaporator coils
- Door jambs, gaskets, hinges and latches
- Table legs
- Bottom sides of work tables
- Carts/trucks-wheels, hubs, fenders
- Employee boots

Step 4: What other factors do you need to consider?

- Product flow
    - Improper Separation of Raw Product Vs. Cooked Product
        - CROSS CONTAMINATION
        - Equipment Usage
        - Product Storage
        - Product Pathways
        - Product Handling
        - Employee Practices
        - Storage
- Equipment use and maintenance
    - Improper Cleaning of Equipment
    - Complex Equipment
    - Shared Equipment and maintenance dept. tools (both Raw and Cooked Product)
- Employee/non-employee Traffic Patterns & Practices (includes maintenance personnel)
    - Improper Employee Traffic Patterns & Practices
        - Slaughter Floor/Raw Processing to RTE Areas
        - NON-EMPLOYEE Traffic
        - Break Room, Restroom, Outdoors
    - Improper Employee Hygiene
        - Working with Raw and Cooked Product at Same Time
        - Personal Practices

        - Clothing
        - Cross Contamination
- Environment
    - Improper Air Flow Through the Exposed Product Area
        - Positive vs. Negative Air Flow and replacement air
        - Air Cooling/Handling Units Not Being Cleaned
    - Improper Use of Cleaning Chemicals, Sanitizers, Tools
        - Cleaning Compound Misuse
        - Sanitizer usage– improper amounts and kinds
        - Using same tools to clean both raw vs. cooked equipment areas
        - Drains not being cleaned
    - Improper Cleaning of Non-contact Area That Affect the Environment
        - Drains
        - Air Cooling Units
        - Equipment Support Structures
        - Knobs, Switches, Handles

What might go wrong with my design for a testing program?

- Improper Sample Sites for Environmental Swabbing
- No Risk Assessment conducted to Determine Sites
- Shared Raw/Cooked Sites Not Selected

Acknowledgement for their input and assistance with Workshop Material

North Carolina Meat and Poultry Inspection Bureau– Dr. Steve Wells, Don Delozier
Iowa Meat and Poultry Inspection Bureau—Janis Hochstetler
North Carolina State University Meat Extension Program– Dr. Dana Hanson
Iowa State University Meat Extension Program– Dr. Joe Cordray, Dr. Gustavo Gonzales
Kansas State University Meat Extension Program- Dr. Liz Boyle
Penn State University Meat Science– Dr. Catherine Cutter

Alternatives 1 and 2 for Control of *Listeria monocytogenes* in Ready-to-Eat Product

Alternatives 1 & 2 for Control for *Listeria monocytogenes*

Components of the Individual Alternatives

1

Alternative 2

- Establishments that choose Alternative 2 will likely be subject to less agency sampling than establishments that choose Alternative 3.
- Alternative 2 would likely be subject to less testing because the risk of contamination in the finished product by *Lm* decreases from Alternative 3 to 2, based on the control methods used by the establishment.

2

Alternative 2

- An establishment that chooses to utilize Alternative 2 in processing its product must apply either:
  - A post-lethality treatment; OR
  - An antimicrobial agent or process that controls the growth of *Lm*

3

Alternative 2

- When using a post-lethality treatment, the establishment must:
  - Include the treatment in the HACCP plan
  - Validate the effectiveness of the treatment per 417.4 of the regulations

4

Alternative 2

- When using an antimicrobial agent or process, the establishment must:
  - Include the treatment in either the HACCP plan or Sanitation SOP (SSOP), or other prerequisite program
  - Document in the HACCP plan, SSOP, or other prerequisite program that the antimicrobial agent or process is effective in suppressing or limiting the growth of *Lm*

5

Alternative 2

- Using only an antimicrobial agent or process, the establishment must:
  - Maintain sanitation in the post-lethality environment according to Part 416
  - Include, in the sanitation program, testing for food contact surfaces in the post-lethality environment to ensure that the surfaces are sanitary and free of *Lm* or its indicator organism (*Listeria* species)
    - An effective sanitation program is important because antimicrobials are not effective at high levels of contamination

6

Alternative 2

Sanitation Program Workshop Discussion

7

Alternative 2

- What do the regulations require to be in the sanitation program to prevent *Lm* contamination on food contact surfaces when using the antimicrobial treatment or process?

8

Alternative 2

- The sanitation program must:
  - Test food contact surfaces in the post-lethality processing environment
  - Indicate the frequency of testing
  - Identify the size and location of the sites to be sampled
  - Include an explanation of why the testing frequency is sufficient to ensure the effective control of *Lm* or its indicator organisms
  - An establishment must implement a hold-and-test procedure for a positive test for *Lm* or its indicator organism

9

Alternative 1

- Establishments that choose Alternative 1 will likely be subject to less agency sampling than establishments that choose either Alternative 2 or 3.
- Alternative 1 would likely be subject to less testing because the risk of contamination in the finished product by *Lm* decreases from Alternative 2 to 1, based on the control methods used by the establishment.

10

Alternative 1

- An establishment that chooses to utilize Alternative 1 in processing its product must apply both:
  - A post-lethality treatment; AND
  - An antimicrobial agent or process that controls the growth of *Lm*

11

Alternative 1

- When using a post-lethality treatment, the establishment must:
  - Include a CCP for the treatment in its HACCP plan that has been validated for effectiveness per 417.4 of the regulations
- When using an antimicrobial agent or process, the establishment must:
  - Include the treatment in its HACCP plan, SSOP, or other prerequisite program

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Alternatives 1 & 2

- Examples of post-lethality treatments
  - Steam/Hot water Pasteurization
  - Pre-Package/Post-Package Surface Pasteurization
  - High Hydrostatic Pressure Processing
  - Ozone
  - Pulse electrical field
  - Organic acids

13

Post-Lethality Treatment

Workshop Discussion

14

Post-Lethality Treatment

- Post-lethality treatment that may be used by small/very small plants.
  - Can anyone provide an example that may be used or that you are using in your establishment?

    (e.g., Hot water pasteurization)

15

Post-Lethality Treatment

- Example, when evaluating a post package product pasteurization process using hot water in a product heating vat
  - What are the important factors to control and monitor for this treatment?

    (e.g., product surface time/temperature profile)

16

Alternatives 1 & 2

- Validation of the post-lethality treatment
  - Specifying and confirming the reduction level achieved by the treatment should be a part of the validation.
  - Points to consider during validation:
    - The post-lethality treatment must be sufficient to eliminate the levels of *Lm* contamination that may occur.
    - Products, treatments, or other variables that are used in the establishments' process should be the same as those used in the published literature, or the treatment should be validated for the plant's specific conditions and product characteristics.

17

Alternatives 1 & 2

- Examples of Outreach Contacts and Resources:
  - University professors
  - University/USDA Extension Service
  - Meat and Poultry Associations
  - University/Public Libraries
  - Agricultural Research Service (ARS) Scientists
  - International HACCP Alliance
  - Equipment Manufacturers
  - Enforcement Regulatory & Analysis Officers (ERAO) (CSO's)
  - Company supplying antimicrobial agents/processes
  - Strategic Initiatives, Partnerships and Outreach (SIPO) Staff (FSIS)
  - FSIS Compliance Guidelines

18

Alternative 1 & 2

- The effectiveness of the post-lethality treatment should be verified by testing for *Lm*
  - Points to consider:
    - Plant data must verify the elimination or reduction of *Lm*?
    - Establishment documentation must support the verification procedures selected and frequency of those procedures?

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Alternatives 1 & 2

- Examples of antimicrobial agents and processes
  - Addition of lactates and diacetates to meat formulations
  - Growth inhibitor packaging
  - Lethality treatment and antimicrobial process that renders RTE product shelf stable (e.g., beef jerky)
  - Freezing during shelf life of RTE product

20

Antimicrobial Agents and Processes

Workshop Discussion

21

Antimicrobial Agent or Process

- Antimicrobial agents or processes that may be used by small/very small plants
  - Can anyone provide an example, other than sodium lactate or freezing, that may be used or that you are using in your establishment?

22

Antimicrobial Agent or Process

- For example, when evaluating a process that renders a RTE product shelf stable
  - The important factors to control and monitor this treatment.
    - Water activity
    - pH

23

Alternatives 1 & 2

- Validation of the antimicrobial agent or process
  - As a part of their validation, the plant should have documentation to demonstrate that the antimicrobial agent or process, as used, is effective in suppressing or limiting the growth of *Lm*
    - For example, the plant should be able to support the reduction levels of the pathogen that the antimicrobial agent or process can achieve, or to what growth suppression level, and length of time in days that the antimicrobial agent or process is effective
  - Points to consider during validation:
    - Documentation must support the use of the particular antimicrobial agent or process

24

Alternatives 1 & 2

- The effectiveness of the antimicrobial agent or process should be verified by testing for *Lm*
  - Points to consider:
    - Plant data must show that the growth of *Lm* is either suppressed or limited
    - Establishment documentation must support the verification procedures selected and frequency of those procedures?

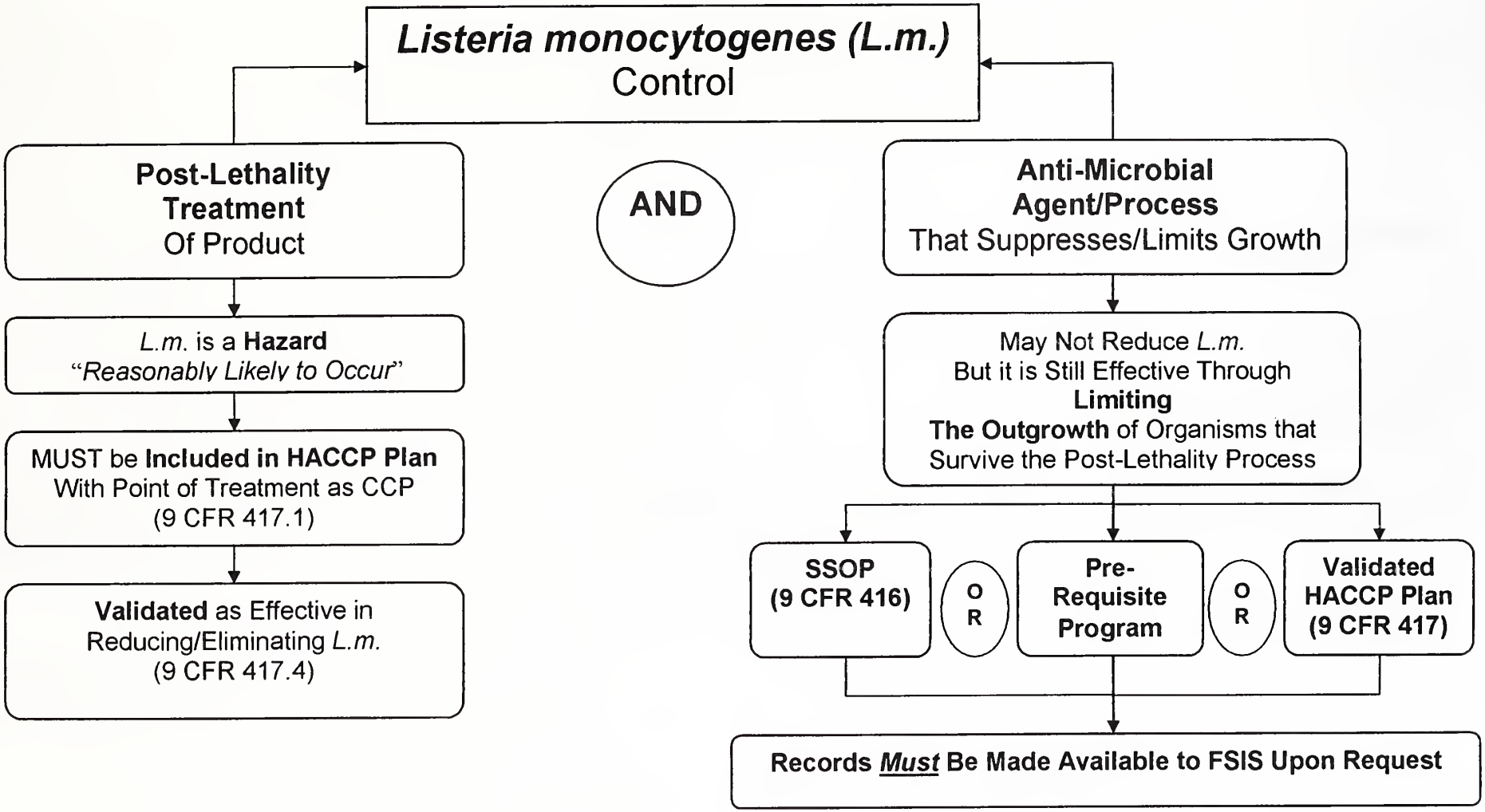
25

CONCLUSION

A General Session For Questions and Answers Will Convene In 15 Minutes

26

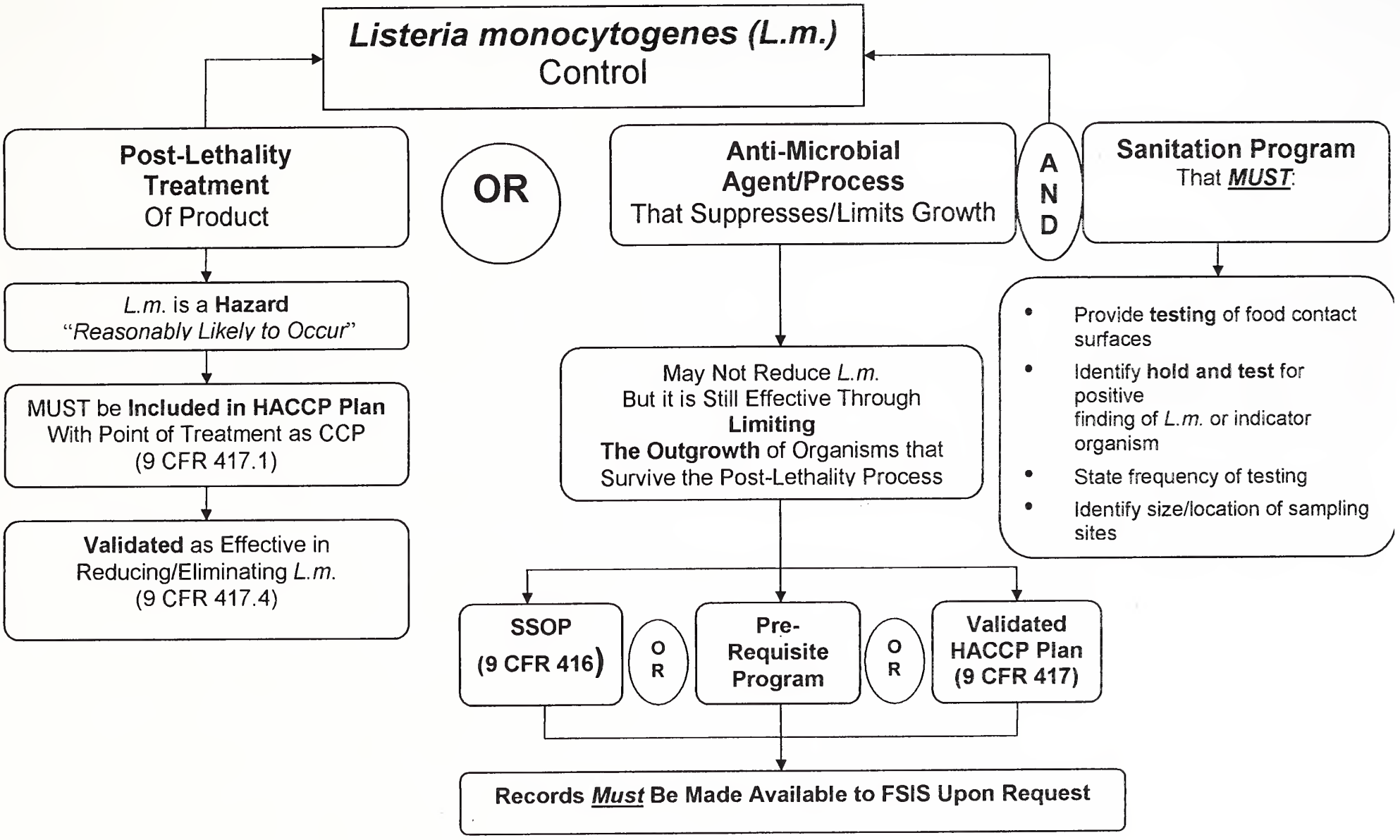
Alternative 1



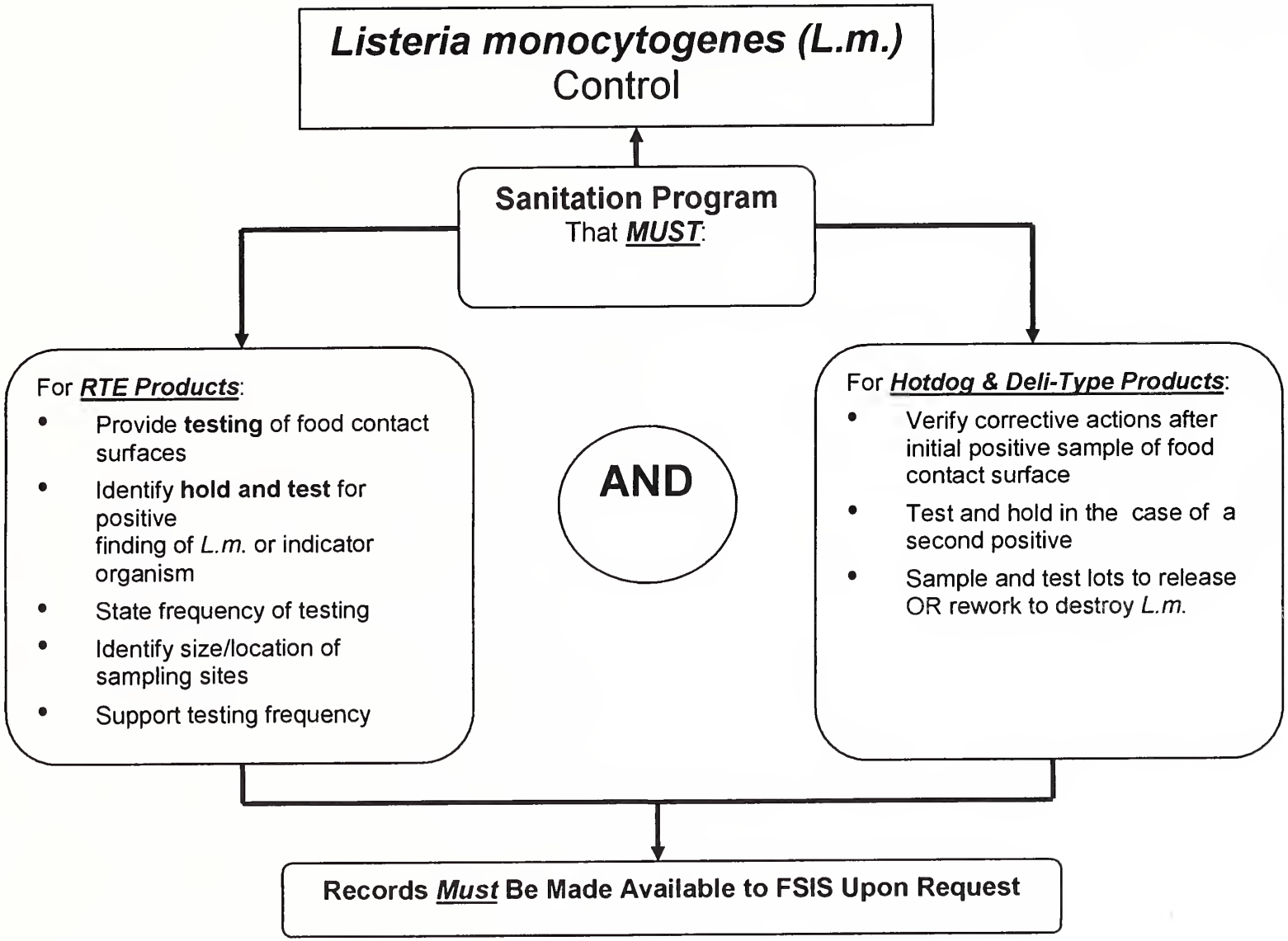
Note:

If an **Anti-Microbial Agent/Process** is Applied as **Part of the Initial Lethality Step AND** Still Has a Continuing Bactericidal Effect on *L.m.* That **Persists** Through Post-Lethality Exposure/Distribution → Can Serve as both Post-Lethality Treatment **AND** Growth-Inhibitor → Establishment ***Must*** Have Supporting Documentation On File

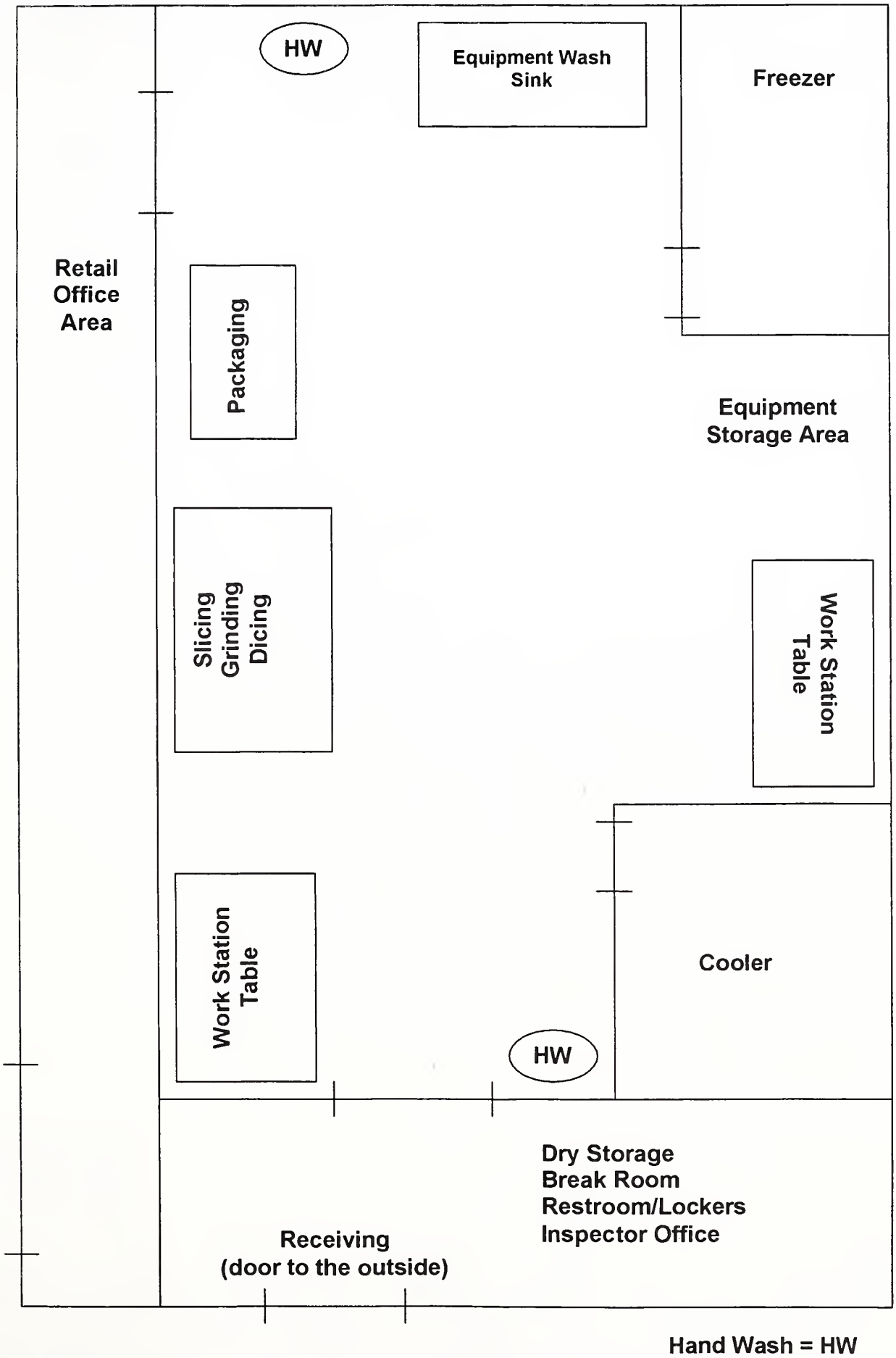
Alternative 2



Alternative 3



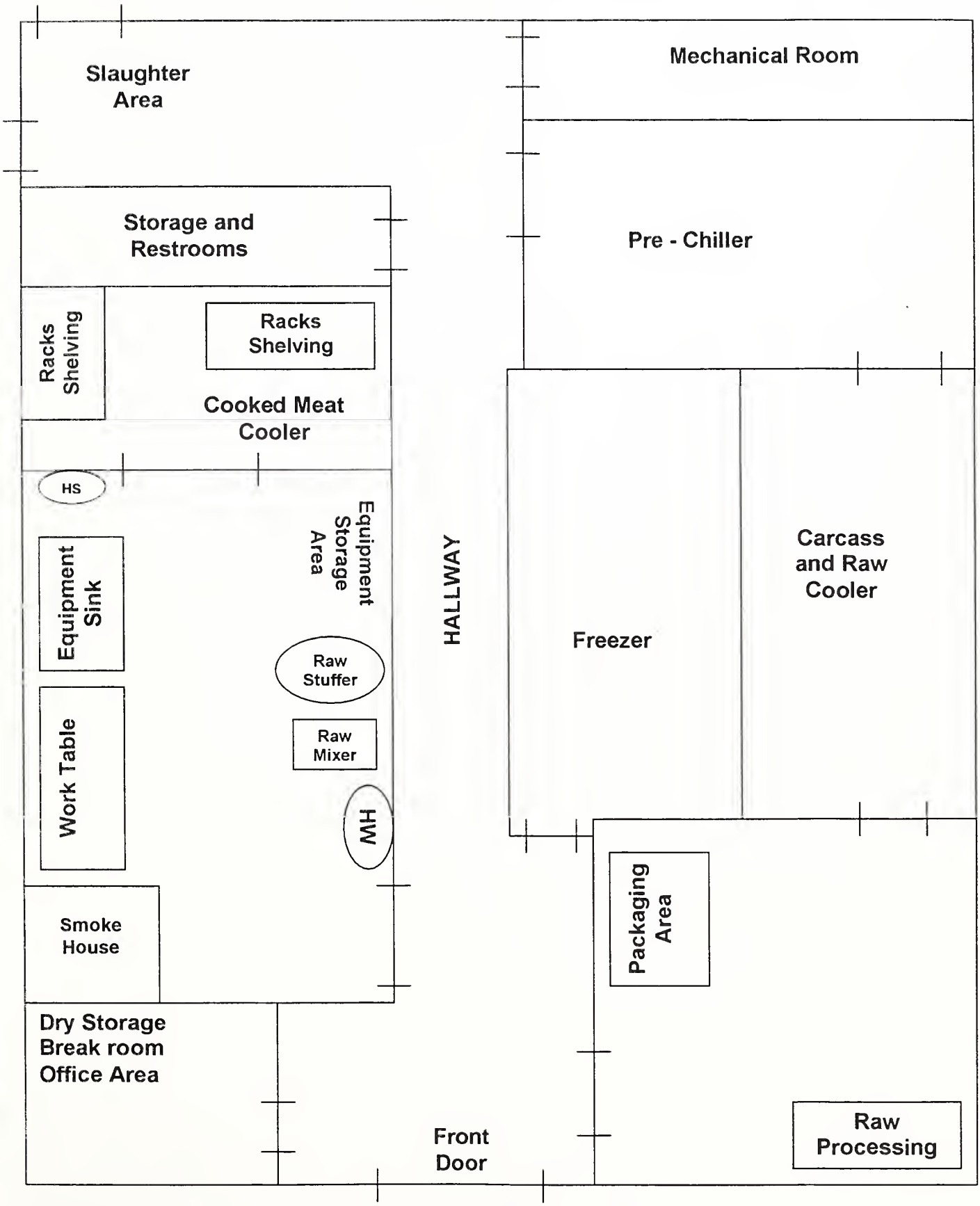
Ready-To-Eat Product Only Plant



Hand Wash = HW

Raw and Ready-to-Eat Plant Layout - Example

HW = Hand Wash HS =Hose Station



Ready-to-Eat Meat and Poultry Product Definitions

READY –TO-EAT MEAT AND POULTRY PRODUCT
PART 430- REQUIREMENTS FOR SPECIFIC CLASSES OF PRODUCT

430.1 DEFINITIONS:

Antimicrobial Agent

A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L.monocytogenes*, or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product. Examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate.

Antimicrobial Process

An operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of microorganisms such as *L. monocytogenes*, in the product throughout the shelf life of the product.

Deli Product

A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption.

Hotdog Product

A ready-to-eat meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181.

Lethality Treatment:

A process, including the application of an antimicrobial agent, that eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments are cooking or application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

Post-lethality Exposed Product

A ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.

Post-lethality Processing Environment

The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Post-lethality Treatment

A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

Additional Ready-to-Eat (RTE) Definition

RTE meat and poultry products are products that have been processed so that they may be safely consumed without further preparation by the consumer (i.e. without cooking or application of some other lethality treatment to destroy pathogens). (66FR 39:12590). (from the draft FSIS Risk Assessment for Listeria in Ready-to-eat Meat and Poultry Products, Feb 03).

EXAMPLES OF RTE PRODUCTS

Dried Products	Basturma, Pastirma, Basturmi. Beef Sticks. Carne Seca. Dried Beef. Dry Duck Breast. Meat/Poultry Jerky.
Salt-Cured Products	Cappicola. Coppa. Country Ham. Dry Cured Duck. Parma Ham. Prosciutto, Prosciutti.
Fermented Products	Alessandri (Dry Sausage). Apenino (Dry Sausage). Arles or D'Arles (Dry Sausage). Blockwurst (Semi-Dry Sausage). Cacciatore/Cacciatora (Dry Sausage). Cervelat. Cervelat, Soft. Chorizo. Lebanon Bologna. Pepperoni. Salami, Soft. Salami: Genoa, Italian, German. Summer Sausage. Thuringer. Thuringer, Soft.
Cooked or Otherwise Processed Whole or Comminuted Products	*Meat* Berliner ;Cooked, Smoked Sausage). Bologna. Bratwurst, Cooked. Braunschweiger/Liver Sausage. Breakfast Link Sausage or Patties. Brown and Serve Sausage. Burritos. Cheese Smokies. Cheesefurter. Cheesewurst/Cheddarwurst. Chili. Chorizo. Cooked Beef. Cooked Ham. Cooked Pork in BBQ Sauce. Cotto Salami. Entrees/Dinners. Fleischkaese (Cured, Cooked Sausage). Frankfurters. Frozen Entrees/Dinners. Gyros. Meat Loaf. Meat Salads. Meat Soups, Frozen. Nem-Chua (Cooked, Pickled Ham with Shredded Pork Skin). Pasta with Meat Sauce. Pastrami. Pickled Pigs Feet in Vinegar. Pickled Sausages/Meat in Vinegar. Piroshki. Pork Barbecue. Pork Sausage Patties. Ravioli. Roast Beef. Roast Pork. Souse. Stews. White Hots. Wieners. *Poultry (Includes Products Containing any Amount of Poultry).* Chicken Burritos. Chicken BBQ. Chicken Bologna. Chicken Breast. Chicken Franks. Cooked Poultry. Cooked Poultry Rolls. Corn Chowder with Chicken. Entrees/Dinners. Poultry Loaf. Poultry Patties. Poultry Rolls. Poultry Salads. Poultry Soups, Frozen. Turkey BBQ. Turkey Franks.
Thermally-Processed, Commercially Sterile Products	Canned Spaghetti with Meat Balls. Canned Corned Beef Hash. Canned Ham. Canned Chicken Salad. Canned Soups with Meat or Poultry.

Listeria monocytogenes Interim Final Rule

PART 430 - REQUIREMENTS FOR SPECIFIC CLASSES OF PRODUCT

Sec. 430.1 Definitions.

Sec. 430.4 Control of Listeria monocytogenes in post-lethality exposed ready-to-eat products.

Authority: 7 U.S.C. 450; 7 U.S.C. 1901-1906; 21 U.S.C. 451-470, 601-695; 7 CFR 2.18, 2.53.

§ 430.1 Definitions.

Antimicrobial agent. A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as L. monocytogenes, or that has the effect of suppressing or limiting growth of L. monocytogenes in the product throughout the shelf life of the product. Examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate.

Antimicrobial process. An operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as L. monocytogenes, in the product throughout the shelf life of the product.

Deli product. A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official

establishment, and typically is assembled in a sandwich for consumption.

Hotdog product. A ready-to-eat meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181.

Lethality treatment. A process, including the application of an antimicrobial agent, that eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments are cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

Post-lethality exposed product. Ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.

Post-lethality processing environment. The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Post-lethality treatment. A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

Prerequisite program. A procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called "prerequisite" because it is considered by scientific experts to be prerequisite to a HACCP plan.

Ready-to-eat (RTE) product. A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear a safe-handling instruction (as required for non-RTE products by 9 CFR 317.2(l) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.

§ 430.4 Control of Listeria monocytogenes in post-lethality exposed ready-to-eat products.

(a) Listeria monocytogenes can contaminate RTE products that are exposed to the environment after they have undergone a lethality treatment. L. monocytogenes is a hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. RTE product is adulterated if it contains L. monocytogenes or if it comes into direct contact with a food contact surface which is contaminated with L. monocytogenes.

(b) In order to maintain the sanitary conditions necessary to meet this requirement, an establishment producing post-lethality exposed RTE product must comply with the requirements included in one of the three following alternatives:

(1) Alternative 1. Use of a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product and an antimicrobial agent or process that suppresses or limits the growth of L. monocytogenes. If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit the growth of the

pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of the post-lethality treatment incorporated in its HACCP plan in accordance with §417.4. The establishment must document, either in its HACCP plan or in its Sanitation SOP or other prerequisite program, that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of L. monocytogenes.

(2) Alternative 2. Use of either a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product or an antimicrobial agent or process that suppresses or limits growth of L. monocytogenes. If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of a post-lethality treatment incorporated in its HACCP plan in accordance with §417.4. The establishment must

document in its HACCP plan or in its Sanitation SOP or other prerequisite program that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of L. monocytogenes.

(iii) If an establishment chooses this alternative and chooses to use only an antimicrobial agent or process that suppresses or limits the growth of L. monocytogenes, its sanitation program must:

(A) provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of L. monocytogenes or of an indicator organism;

(B) identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for L. monocytogenes or an indicator organism;

(C) state the frequency with which testing will be done;

(D) identify the size and location of the sites that will be sampled; and

(E) include an explanation of why the testing frequency is sufficient to ensure that effective control of L. monocytogenes or of indicator organisms is maintained.

(iv) An establishment that chooses this alternative and uses a post-lethality treatment of product will likely be subject to more frequent verification testing by FSIS than if it had chosen Alternative 1. An establishment that chooses this alternative and uses an antimicrobial agent or process that suppresses or limits the growth of L. monocytogenes will likely be subject to more frequent FSIS verification testing than if it uses a post-lethality treatment.

(3) Alternative 3. Use of sanitation measures only.

(i) If an establishment chooses this alternative, its sanitation program must:

(A) provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of L. monocytogenes or of an indicator organism;

(B) identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for L. monocytogenes or an indicator organism;

(C) state the frequency with which testing will be done;

(D) identify the size and location of the sites that will be sampled; and

(E) include an explanation of why the testing frequency is sufficient to ensure that effective control of L. monocytogenes or of indicator organisms is maintained.

(ii) An establishment producing a deli product or a hotdog product, in addition to meeting the requirements of paragraph (b)(3)(i) of this section, must meet the following requirements:

(A) The establishment must verify that the corrective actions that it takes with respect to sanitation after an initial positive test for L. monocytogenes or an indicator organism on a food contact surface in the post-lethality processing environment are effective by conducting follow-up testing that includes a targeted test of the specific site on the food contact surface area that is the most likely source of contamination by the organism and such additional tests in the surrounding food contact surface area as are necessary to ensure the effectiveness of the corrective actions.

(B) During this follow-up testing, if the establishment obtains a second positive test for L. monocytogenes or an indicator organism, the establishment must hold lots of product that may have become contaminated by contact with the food contact surface until the

establishment corrects the problem indicated by the test result.

(C) Further, in order to be able to release into commerce the lots of product that may have become contaminated with L. monocytogenes, the establishment must sample and test the lots for L. monocytogenes or an indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with L. monocytogenes. The establishment must document the results of this testing. Alternatively, the establishment may rework the held product using a process that is destructive of L. monocytogenes or the indicator organism.

(iii) An establishment that chooses Alternative 3 is likely to be subject to more frequent verification testing by FSIS than an establishment that has chosen Alternative 1 or 2. An establishment that chooses Alternative 3 and that produces deli meat or hotdog products is likely to be subject to more frequent verification testing than one that does not produce such products.

(c) For all three alternatives in paragraph (b):

(1) Establishments may use verification testing that includes tests for L. monocytogenes or an indicator organism, such as Listeria species, to verify the

effectiveness of their sanitation procedures in the post-lethality processing environment.

(2) Sanitation measures for controlling L. monocytogenes and procedures for antimicrobial agents or processes that suppress or limit the growth of the pathogen may be incorporated either in the establishment's HACCP plan or in its Sanitation SOP or other prerequisite program. When these control procedures are incorporated into the Sanitation SOP or prerequisite program, and not as a CCP in the HACCP plan, the establishment must have documentation that supports the decision in its hazard analysis that L. monocytogenes is not a hazard that is reasonably likely to occur.

(3) The establishment must maintain sanitation in the post-lethality processing environment in accordance with part 416.

(4) If L. monocytogenes control measures are included in the HACCP plan, the establishment must validate and verify the effectiveness of measures for controlling L. monocytogenes included in its HACCP plan in accordance with §417.4.

(5) If L. monocytogenes control measures are included in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with §416.14.

(6) If the measures for addressing L. monocytogenes are addressed in a prerequisite program other than the Sanitation SOP, the establishment must include the program and the results produced by the program in the documentation that the establishment is required to maintain under 9 CFR 417.5.

(7) The establishment must make the verification results that demonstrate the effectiveness of the measures it employs, whether under its HACCP plan or its Sanitation SOP or other prerequisite program, available upon request to FSIS inspection personnel.

(d) An establishment that produces post-lethality exposed RTE product shall provide FSIS, at least annually, or more often, as determined by the Administrator, with estimates of annual production volume and related information for the types of meat and poultry products processed under each of the alternatives in paragraph (b) of this section.

(e) An establishment that controls L. monocytogenes by using a post-lethality treatment or an antimicrobial agent or process that eliminates or reduces, or suppresses or limits the growth of the organism may declare this fact on the product label provided that the establishment has validated the claim.

Ready-to-Eat Examples Reclassified

RTE Examples – Reclassified	
Deli Meats	Bologna. Cappicola. Cervelat, Soft. Cervelat. Chicken Bologna. Cooked Beef. Cooked Ham Coppa. Cotto Salami. Lebanon Bologna. Parma Ham. Pastrami. Pepperoni. Poultry Loaf. Prosciutto, Prosciutti. Roast Beef. Roast Pork. Salami, Soft. Salami: Genoa, Italian, German. Souse. Summer Sausage. Thuringer, Soft. Thuringer.
Dinners	Dinners have at lease 3 separate components and weight 10 ounces or more. The component names will be part of the product name, e.g., fried chicken, mashed potatoes and green beans.
Entrees	Entrees are the principal dish or main course : Burritos. Chicken BBQ. Chicken Breast. Chicken Burritos. Chili. Cooked Ham. Cooked Pork in BBQ Sauce. Cooked Poultry Rolls. Cooked Poultry. Corn Chowder with Chicken. Country Ham. Dry Cured Duck. Gyros. Meat Loaf. Meat Salads. Meat Soups, Frozen. Nem-Chua (Cooked, Pickled Ham with Shredded Pork Skin).

	Pasta with Meat Sauce. Pickled Pigs Feet in Vinegar. Pickled Sausages/Meat in Vinegar. Piroshki. Pork Barbecue. Pork Sausage Patties. Poultry Patties. Poultry Rolls. Poultry Salads. Poultry Soups, Frozen. Ravioli. Roast Beef. Stews. Turkey BBQ. White Hots. Multiple component entrees; The component names will be part of the product name, e.g., salisbury steak smothered in gravy with mixed vegetables.
Hotdog Products	Chicken Franks. Frankfurters. Turkey Franks Wieners.
Other non-sliced sausage	Braunschweiger/Liver Sausage. Breakfast Link Sausage or Patties. Brown and Serve Sausage. Alessandri (Dry Sausage). Apenino (Dry Sausage). Arles or D'Arles (Dry Sausage). Berliner (Cooked, Smoked Sausage). Blockwurst (Semi-Dry Sausage). Bratwurst, Cooked. Cacciatore/Cacciatora (Dry Sausage). Cheese Smokies. Cheesefurter. Cheesewurst/Cheddarwurst. Chorizo. Chorizo. Fleischkaese (Cured, Cooked Sausage). Pepperoni. Pickled Sausages/Meat in Vinegar
Snacks / Hors D'Oeuvre	Basturma, Pastirma, Basturmi. Beef Sticks. Carne Seca. Dried Beef. Dry Duck Breast. Meat/Poultry Jerky.
Thermally-Processed, Commercially Sterile Products	Canned Spaghetti with Meat Balls. Canned Corned Beef Hash. Canned Ham. Canned Chicken Salad. Canned Soups with Meat or Poultry.

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY [1,2,3,4,5]

Product category	Reference amount	Reference amount
	Ready-to-serve	Ready-to-cook
Egg mixtures, (western style omelet, souffle, egg foo young	110 g	n/a.
Lard, margarine, shortening	1 tbsp	n/a.
Salad and potato toppers; e.g., bacon bits	7 g	n/a.
Bacon (bacon, beef breakfast strips, pork breakfast strips, pork rinds)	15 g	54 g=bacon. 30 g = breakfast strips.
Dried; e.g., jerky, dried beef, Parma ham sausage products with a moisture/protein ratio of less than 2:1; e.g., pepperoni.	30 g	n/a.
Snacks; e.g., meat snack food sticks	30 g	n/a.
Luncheon meat, bologna, Canadian style bacon, pork pattie crumbles, beef pattie crumbles, blood pudding, luncheon loaf, old fashioned loaf, berlinger, bangers, minced luncheon roll, thuringer, liver sausage, mortadella, uncured sausage (franks), ham and cheese loaf, P&P loaf, scrapple souse, head cheese, pizza loaf, olive loaf, pate, deviled ham, sandwich spread, teawurst, cervelet, Lebanon bologna, potted meat food product, taco fillings, meat pie fillings.	55 g	n/a.
Linked meat sausage products, Vienna sausage, frankfurters, pork sausage, imitation frankfurters, bratwurst, kielbasa, Polish sausage, summer sausage, mettwurst, smoked country sausage, smoked sausage, smoked or pickled meat, pickled pigs feet.	55 g	n/a. 75 g=uncooked sausage.
Entrees without sauce, cuts of meat including marinated, tenderized, injected cuts of meat, beef patty, corn dog, croquettes, fritters, cured ham, dry cured ham, dry cured cappicola, corned beef, pastrami, country ham, pork shoulder picnic, meatballs, pureed adult foods.	85 g	114 g.
Canned meats, canned beef, canned pork. [4]	55 g	n/a.
Entrees with sauce, barbecued meats in sauce	140 g	n/a.
Mixed dishes NOT measurable with a cup; [5] e.g., burrito, egg roll, enchilada, pizza, pizza roll, quiche, all types of sandwiches, cracker and meat lunch type packages, gyro, stromboli, burger on a bun, frank on a bun, calzone, taco, pockets stuffed with meat, foldovers, stuffed vegetables with meat, shish kabobs, empanada.	140 g (plus 55 g for products with sauce toppings)	n/a.
Mixed dishes measurable with a cup; e.g., meat casserole, macaroni and cheese with meat, pot pie, spaghetti with sauce, meat chili, chili with beans, meat hash, creamed chipped beef, beef ravioli in sauce, beef stroganoff, Brunswick stew, goulash, meat stew, ragout, meat lasagna, meat filled pasta.	1 cup	n/a.
Salads—pasta or potato, potato salad with bacon, macaroni and meat salad	140 g	n/a.
Salads—all other meat, salads, ham salad	100 g	n/a.
Soups—all varieties	245 g	n/a.
Major main entree type sauce; e.g., spaghetti sauce with meat, spaghetti sauce with meatballs.	125 g	n/a.
Minor main entree sauce; e.g., pizza sauce with meat, gravy	¼ cup	n/a.
Seasoning mixes dry, bases, extracts, dried broths and stock/juice, freeze dry trail mix products with meat..		
As reconstituted:		
Amount to make one Reference Amount of the final dish; e.g.,		
Gravy	¼ cup	n/a.
Major main entree type sauce	125 g	n/a.
Soup	245 g	n/a.
Entree measurable with a cup	1 cup	n/a.

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–78 and the 1987–88 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Manufacturers are required to convert the Reference Amounts to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.

[3] Examples listed under Product Category are not all inclusive or exclusive. Examples are provided to assist manufacturers in identifying appropriate product Reference Amount.

[4] If packed or canned in liquid, the Reference Amount is for the drained solids, except for products in which both the solids and liquids are customarily consumed.

[5] Pizza sauce is part of the pizza and is not considered to be sauce topping.

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY [1,2,3,4,5]

Product category	Reference Amount Ready-to-serve	Reference Amount Ready-to-cook
Egg mixtures, (western style omelet, souffle, egg foo young with poultry).	110 g	n/a
Salad and potato toppers; e.g., poultry bacon bits	7 g	n/a
Bacon; e.g., poultry breakfast strips.	15 g	26 g = bacon. 18 g = breakfast strips
Dried; e.g., poultry jerky, dried poultry, poultry sausage products with a moisture/protein ratio of less than 2:1.	30 g	n/a
Snacks; e.g., poultry snack food sticks	30 g	n/a
Luncheon products, poultry bologna, poultry Canadian style bacon, poultry crumbles, poultry luncheon loaf, potted poultry products, poultry taco fillings.	55 g	n/a
Linked poultry sausage products, poultry franks. poultry Polish sausage, smoked or pickled poultry meat, poultry smoked sausage.	55 g	n/a 69 g = uncooked sausage.
Entrees without sauce, poultry cuts, ready to cook poultry cuts, including marinated, tenderized, injected cuts of poultry, poultry corn dogs, poultry croquettes, poultry fritters, cured poultry ham products, adult pureed poultry.	85 g	114g
Canned poultry, canned chicken, canned [4] turkey	55 g	n/a
Entrees with sauce, turkey and gravy	140 g	n/a
Mixed dishes NOT measurable with a cup; [5] e.g., poultry burrito, poultry enchiladas, poultry pizza, poultry quiche. all types of poultry sandwiches, cracker and poultry lunch-type packages, poultry gyro, poultry stromboli, poultry frank on a bun, poultry burger on a bun, poultry taco, chicken cordon bleu, poultry calzone, stuffed vegetables with poultry, poultry kabobs.	140 g (plus 55 g for products toppings)	n/a
Mixed dishes, measurables with a cup; e.g., poultry casserole, macaroni and cheese with poultry, poultry pot pie, poultry spaghetti with sauce, poultry chill, poultry chili with beans, poultry hash, creamed dried poultry, poultry ravioli in sauce, poultry a la king, poultry stew, poultry goulash, poultry lasagna, poultry-filled pasta.	1 cup	n/a
Salads—pasta or potato, potato salad with poultry, macaroni and poultry salad.	140 g	n/a
Salads—all other, poultry salads, chicken salad, turkey salad	100 g	n/a
Soups—all varieties	245 g	n/a
Major main entree type sauce; e.g., spaghetti sauce with poultry	125 g	n/a
Minor main entree sauce; e.g., pizza sauce with poultry, gravy	¼ cup	n/a
Seasoning mixes dry, freeze dry, dehydrated, concentrated soup mixes, bases, extracts, dried broths and stock/juice, freeze dry trail mix products with poultry.		
As reconstituted: Amount to make one Reference Amount of the final dish; e.g.—		
Gravy	¼ cup	n/a
Major main entree type sauce	125 g	n/a
Soup	245 g	n/a
Entree measurable with a cup	1 cup	n/a

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–78 and the 1987–88 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Manufacturers are required to convert the Reference Amounts to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.

[3] Examples listed under Product Category are not all inclusive or exclusive. Examples are provided to assist manufacturers in identifying appropriate product Reference Amount.

[4] If packed or canned in liquid, the Reference Amount is for the drained solids, except for products in which both the solids and liquids are customarily consumed.

[5] Pizza sauce is part of the pizza and is not considered to be a sauce topping.

TYPE	CLASS	PROCESSING CATEGORY ISP CODE	REG REQUIRED SAFETY LABELING	WHAT THE HAZARD ANALYSIS/HACCP PLAN MAY ADDRESS
A product containing a meat/poultry product (in whole or in part) which has not received an adequate lethality treatment for pathogens (i.e. raw or partially cooked product).	Not-ready-to-eat	• Raw Product Ground – ISP 03B • Raw Product Not Ground – ISP 03C • Not Heat Treated Shelf Stable – ISP 03E • Heat Treated –shelf stable – ISP 03F • Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H • Products with secondary inhibitors Not Shelf Stable – ISP 031 •	Product must be labeled with statements such as keep refrigerated, keep frozen, or refrigerate leftovers. Use of Safe Handling Instruction (SHI) labeling required.	• Use of SHI labeling (Some establishments may have a CCP for SHI labeling application). If it is not obvious that the product is raw and needs to be cooked: • Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., "Cook and Serve") but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as "needs to be fully cooked," "see cooking instructions," or "cook before eating." • Validation that: a. Cooking and preparation instructions on the product are sufficient to destroy pathogens. b. Instructions are realistic for the intended consumer.
A product containing a meat/poultry component that has received a lethality treatment for pathogens in combination with non-meat/poultry components that need to receive a lethality treatment by the intended user. This includes meals, dinners, and frozen entrees.	Not-ready-to-eat	• Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H	Product must be labeled with statements such as keep refrigerated or frozen. Use of SHI labeling is recommended.	• Validation that: a. The meat/poultry component received an adequate lethality treatment for pathogens. b. Cooking and preparation instructions on the product are sufficient to destroy pathogens. c. Instructions are realistic for the intended consumer. • Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., "Cook and Serve") but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as "needs to be fully cooked," "see cooking instructions," or "cook before eating." • If necessary, hazard analysis should address whether instructions on the label are needed related to cross-contamination (e.g., avoid contact of contents) and prevention of pathogenic growth (e.g., promptly refrigerate leftovers). NOTE: Inspection program personnel are to collect samples as RTE if the establishment does not follow the guidance above.
A product containing a meat/poultry component that has received a lethality treatment for pathogens that may or may not be in combination with a non-meat/ poultry component that does not need to receive a lethality treatment by the intended user.	Ready-to-eat	• Not Heat Treated Shelf Stable – ISP 03E • Heat Treated Shelf Stable – ISP 03F • Fully Cooked Not Shelf Stable – ISP 03G • Products with secondary inhibitors Not Shelf Stable – ISP 031	If the product is not shelf stable labeling such as keep refrigerated or frozen is required.	• See part 417 of the meat and poultry regulations.

Compliance Guidelines

COMPLIANCE GUIDELINES TO CONTROL *LISTERIA MONOCYTOGENES* IN POST-LETHALITY EXPOSED READY-TO-EAT MEAT AND POULTRY PRODUCTS

Table of Contents

The Compliance Guidelines

FSIS developed this Compliance Guidelines to help the establishments producing Ready-to-Eat (RTE) meat and poultry products, especially small and very small establishments, in its use of control methods for *L. monocytogenes* to comply to the requirements of 9 CFR 430. Its purpose is to show establishments what the control methods can achieve, if used singly or in combination, to prevent or eliminate *L. monocytogenes* contamination in the product during post-lethality exposure. Establishments can use the guidelines to determine control methods that are best suited to their processing. Some establishments may have already instituted their control methods, which they have verified to be effective in controlling the pathogen and may not need to change their methods to follow these guidelines. However, FSIS will make a determination on the effectiveness of the controls and establishment verification testing when deciding how FSIS will conduct verification in the establishment.

These guidelines were updated from the version posted on the FSIS website in June 2003. The updated version includes the levels of reduction of *L. monocytogenes* achieved by the post-lethality treatment and the levels of growth suppression of *L. monocytogenes* achieved by the antimicrobial agent or process that will likely be considered for Alternatives 1 and 2 for purposes of this rule, and the levels that will likely be eligible for application of labeling claim of enhanced protection for *L. monocytogenes*. A chart of most likely frequency of verification sampling by FSIS and the effective controls achieved by the methods used by establishments for each Alternative is added to update the guidelines. The following were also added in the attachments: 1) a systematic table presenting the requirements of the 3 Alternatives; 2) a table to differentiate RTE products from not RTE products; 3) an example of the ICMSF sampling plan that provides a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes;* and 4) a schematic diagram and flowchart of a hold-and-test scenario. These guidelines will be updated further as necessary to include validated and other effective procedures as they become available.

A. Requirements of the Rule

Listeria monocytogenes is a pathogen that is widely distributed in the environment such as plant, soil, animal, water, dirt, dust, and silage. Because *L. monocytogenes* can be found in slaughter animals and in raw meat and poultry and other ingredients, it can be continuously introduced in the processing environment. The pathogen can cross-contaminate food contact surfaces, equipment, floors, drains, standing water and employees. In addition, the pathogen can grow in damp environments and can establish a niche and form biofilms in the processing environment that is difficult to eliminate during cleaning and sanitizing. Other characteristics of *L. monocytogenes* that makes it a formidable pathogen to control are its heat and salt tolerance and its ability to grow at refrigeration temperatures.

The lethality treatment received by processed ready-to-eat (RTE) meat and poultry products eliminates *L. monocytogenes,* however products can be re-contaminated by exposure after the lethality treatment during peeling, slicing, repackaging, and other

procedures. Several foodborne illnesses resulting in hospitalization, miscarriage and death have been linked to the consumption of deli meats and hotdogs containing *L. monocytogenes*. The cause of *L. monocytogenes* contamination in these outbreaks was traced to post-lethality exposure and contamination by the pathogen. Deli and hotdog products are examples of RTE meat and poultry products that receive a lethality treatment to eliminate pathogens, and are subsequently exposed to the environment during peeling, slicing, and repackaging operations. If *L. monocytogenes* is present in the equipment used for peeling, slicing or repackaging, the pathogen can be transferred to the product upon contact. These products are examples of RTE meat and poultry products that can support the growth of *L. monocytogenes* during refrigerated storage. Since RTE products are consumed without further cooking for safety, there is a possibility of the occurrence of foodborne illness. The "FDA/FSIS Draft Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods" (www.cfsan.fda.org) indicated that deli meats and hotdogs posed the greatest per serving risk of illness/death from L. monocytogenes.

RTE meat and poultry processing plants must include control programs for *Listeria monocytogenes* in their HACCP plans, Sanitation SOP or prerequisite programs to prevent its growth and proliferation in the plant environment and equipment, and cross-contamination of RTE products. The FSIS *Listeria* risk assessment (www.fsis.usda.gov/OPHS/lmrisk/DraftLm.22603) indicated that the use of a combination of intervention methods to control *L. monocytogenes* in (deli meats) exposed to the environment after the lethality treatment has the greatest impact on lowering the risk of illness or death from *L. monocytogenes*. The Agency used these risk assessments as references in developing the regulations to control *L. monocytogenes* in RTE meat and poultry processing.

The rule for the control of *Listeria monocytogenes* (9 CFR 430) includes three alternative methods that establishments can use in the processing of RTE meat and poultry products during post-lethality exposure. Alternative 1 requires an establishment to apply a post-lethality treatment and an antimicrobial agent or process to control *L. monocytogenes*. Alternative 2 requires an establishment to apply either a post-lethality treatment or an antimicrobial agent or process. In Alternative 3, the establishment does not apply any post-lethality treatment or antimicrobial agent or process, so it is required to have a sanitation program that includes testing food contact surfaces and holding product when tests turn out positive. Products in Alternative 1 and 2 are formulated and processed to eliminate L. monocytogenes or limit its growth should it be present, and provides the greatest control as compared to Alternative 3 which uses a sanitation and testing program to control *L. monocytogenes*. Consequently, the risk for contamination by the pathogen increases from Alternative 1 to 3, based on rigor or stringency of the control methods used by the establishment. An establishment must identify which alternative their RTE product falls into based on its control program for *L. monocytogenes*. An establishment can choose to apply new control methods and move from one Alternative to another, however, it must apply the control methods required for the specific Alternative in its processing so it can qualify for the Alternative. Each Alternative has requirements that

the establishment must comply to. A systematic table of the requirements for each alternative can be found in Attachment 1.

Alternative 1

Alternative 1 requires the use of post-lethality treatment (which maybe an antimicrobial agent) to reduce or eliminate *L. monocytogenes* and an antimicrobial agent or process to suppress or limit the growth of the pathogen. For RTE products that are cooked and then removed from their cooking bag and sliced, diced or repackaged, there is a risk of cross contamination from the equipment, conveyor belts and the environment. These products need to be aseptically processed and then repackaged under strict sanitary conditions to prevent contamination from *L. monocytogenes*. Post lethality treatments such as steam pasteurization, hot water pasteurization, radiant heating and high pressure processing have been developed to prevent or eliminate post-processing contamination by *L. monocytogenes*. RTE products where post-lethality treatments were shown by studies to be effective in reducing the level of *L. monocytogenes* are whole or formed ham, whole and split roast beef, turkey ham, chicken breast fillets and strips, and sliced ham, sliced turkey, and sliced roast beef.

Examples of antimicrobial agents shown to inhibit listerial growth are lactates and diacetates added in the formulation and the use of growth inhibitors in the immediate packaging material. Some growth inhibitor packaging and some levels and combinations of antimicrobial agents were shown by research studies to reduce the levels of *L. monocytogenes*. RTE products where studies on antimicrobial agents were shown to be effective in the control *L. monocytogenes* are hot dogs, bologna, cotto salami, and bratwurst.

An establishment whose product or process falls in Alternative 1 must have the post-lethality treatment that reduces or eliminates the pathogen in its HACCP plan. The post-lethality treatment must be validated according to 9CFR 417.4 as being effective in reducing or eliminating *L. monocytogenes* and the validation should specify the log reduction achieved by the post-lethality treatment and antimicrobial agents. The effectiveness of the post-lethality treatments and antimicrobial agents must be verified and have the verification results available to FSIS personnel upon request.

The antimicrobial agent or process that limits or suppresses *L. monocytogenes* must be included in the establishment's HACCP plan, or sanitation SOP, or other prerequisite program. The establishment must have documentation in its HACCP plan, Sanitation SOP or other prerequisite program to demonstrate that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes*. The establishment must validate and verify the effectiveness of its antimicrobial agent or process included in its HACCP plan in accordance with § 417.4. If the antimicrobial agent or process is in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with 416.14. If the control measures for *L. monocytogenes* are contained in a prerequisite program other than a Sanitation SOP, the program must ensure

that the program is effective and does not cause the hazard analysis or the HACCP plan to be inadequate. The establishment must include the program and the results produced by the program in the documentation that the establishment is required to maintain under 9 CFR 417.5.

Post-lethality treatments can be applied as a pre-packaging treatment, e.g. radiant heating, or as post-packaging treatments, e.g., hot water pasteurization, steam pasteurization, and high pressure processing. Some of the studies on post-lethality treatments are reviewed in section B. Establishments should refer to the details of the studies if they want to use the intervention method in their processing. The guidelines will be updated to include studies or other methods as they become available. Studies on post-lethality treatments showed reductions of inoculated *L. monocytogenes* from 1 to 7 $\log_{10}$ CFU/g depending on the product type, and duration, temperature and pressure of treatment. Higher log reductions were obtained when both pre-packaging and post-packaging surface pasteurizations were applied, and when post-lethality pasteurization was combined with the use of antimicrobial agents.

An establishment can use available published research studies as reference for their validation provided it uses the product type or size, the type of equipment, time, temperature, pressure and other variables used in the study in order to result in the same level of reduction of *L. monocytogenes*. An establishment that uses products, treatments or variables other than those used in the studies must perform its own validation studies to determine the effective reduction of *L. monocytogenes* as a result of the post-lethality treatment or antimicrobial agent applied to the products. Some of the published studies use different products and report a range of levels of reduction of *L. monocytogenes*. In this case, the establishment must validate the use of the post-lethality treatment or antimicrobial agent for their specific products. The establishment must specify the level of reduction achieved by the post-lethality treatment or antimicrobial agent applied in their validation. Aside from validation of the post-lethality treatment and antimicrobial agent, the establishment must verify its effectiveness by testing for *L. monocytogenes*.

Antimicrobial agents can be added to the product during formulation, to the finished product or to the packaging material to inhibit growth of *L. monocytogenes* in the post-lethality exposed product during its refrigerated shelf life. Lactates and diacetates are some antimicrobials added to the formulation of RTE meat and poultry products. Establishments should use antimicrobial agents that have been approved by FDA and FSIS for processed RTE meat and poultry products. Approved antimicrobial agents for processed meat and poultry products can be found in 9 CFR 424.21.

Studies on antimicrobials added to the packaging material or active packaging showed about 1-2 $\log_{10}$ CFU/g reduction of *L. monocytogenes* during the refrigerated shelf life of the products. Based on published studies, growth reduction or inhibition achieved by adding these antimicrobials to product formulation depends on a variety of factors, such as the level of antimicrobial agent added, product formulation and whether added during formulation or the finished product. Depending on the amount of antimicrobials and other growth inhibitors added to the product formulation and other ingredients in the

product, growth inhibition of *L. monocytogenes* was shown to range from 30 days to 120 days at refrigerated temperatures. Some published studies on antimicrobials are reviewed in section C. Establishments should refer to the details of the studies if they want to use the intervention method in their processing.

An example of an antimicrobial process that controls the growth of *L. monocytogenes* in the post-lethality environment is a lethality process that renders a RTE product shelf stable. Shelf stable products are formulated with salt, nitrites and other additives, and processed to achieve a water activity, pH and moisture-protein ratio that will reduce the level of *L. monocytogenes* and other pathogens during processing. In addition, the lethality treatment exerts a continuing bactericidal and bacteriostatic effect and does not support the growth of *L. monocytogenes* and other pathogens during the shelf life of the product at ambient temperatures. In this case, the antimicrobial process could serve as both a post-lethality treatment and growth inhibitor. The establishment should have documentation on file to demonstrate the effectiveness of the lethality treatment through the shelf life of the product. These shelf stable products can be classified in Alternative 1, and need to satisfy the requirements for this Alternative. Examples of shelf stable RTE products are country cured ham, pepperoni, salami, and jerky.

Some of these products with added salt, nitrites and other additives achieve a water activity, pH, or moisture-protein-ratio that will reduce the level of *L. monocytogenes* and other pathogens during processing and continue to inhibit the growth of the pathogens during the refrigerated shelf life. These products are not shelf stable because they need to be refrigerated during their shelf life, but because of the water activity and pH attained during the initial lethality treatment, these products may not support the growth of *L. monocytogenes* during its refrigerated shelf life. These products can classify as using an antimicrobial agent or process. Examples of these products are not shelf stable fermented sausages and country cured hams.

Another antimicrobial process that controls the growth of *L. monocytogenes* in the post-lethality environment is freezing of RTE products. Freezing prevents the growth of any microorganisms in the product because their metabolic activities are arrested, but depending on the method and length of freezing and other factors, some microbial kill can also result. Like other microorganisms, *L. monocytogenes* is resistant to freezing. Once the product is thawed, metabolic activities of microorganisms may resume, depending on whether the microorganisms are killed, injured, or not affected at all. Therefore this antimicrobial process is only effective while the product is frozen. Labels of RTE frozen products contain cooking instructions for the frozen product and for thawed and refrigerated product, and instructions for thawing at refrigerated temperatures. Examples of frozen RTE products are fully cooked frozen chicken nuggets, fully cooked frozen chicken breast patties or fully cooked frozen dinners.

The establishment can include the antimicrobial treatment that limits or suppresses *L. monocytogenes* in the HACCP plan, Sanitation SOP or prerequisite program. However, the establishment must show the effectiveness of the antimicrobials in suppressing or limiting *L. monocytogenes* in these programs. An establishment can use published studies

as reference for its validation as long as it uses the same treatment variables as those used in the study. These variables include among others, specific antimicrobial agents, concentration, time and temperature of effectiveness and others. Use of antimicrobial singly or in combination, with different concentration and other variables, and for products not used in the studies must be validated or tested for their effectiveness. This must be validated for the HACCP plan, or documented in the Sanitation SOP or other prerequisite programs. The establishment must verify that the antimicrobial program is effective by testing product for *L. monocytogenes* and must verify that it does not cause the hazard analysis or the HACCP plan to be inadequate.

An establishment with products in Alternative 1 must maintain sanitation in the post-lethality processing environment in accordance with part 416. The establishment must make the verification results that demonstrate the effectiveness of its controls, whether from carrying out its HACCP plan, or its Sanitation SOP, or other prerequisite program, available upon request to FSIS inspection personnel.

Establishments have been using prerequisite programs before in their processing operations, and the Agency has recently included the use of prerequisite programs as an option in another policy document. However, giving the establishment the option to include the antimicrobial agent or process in a prerequisite program in this rule is the first time prerequisite programs are recognized in codified regulations.

An establishment with products in Alternative 1 must have a post-lethality treatment that effectively reduces or eliminates *L. monocytogenes*, and an antimicrobial agent or process that suppresses any growth of the pathogen and extends the effect of the post-lethality treatment during the shelf life of the product. The Agency considers these treatments to be effective in controlling the pathogen to result in a safe RTE product. If an establishment has an effective Sanitation SOP, any post-lethality contamination by *L. monocytogenes* would be very small, so the post-lethality treatment and the antimicrobial will be able to reduce or eliminate this contamination. If there is gross contamination, the effectiveness of the treatments may be reduced or negated. Therefore the Agency is relying on the establishment's Sanitation SOP to prevent contamination with *L. monocytogenes*, and the post-lethality treatment and antimicrobials to further reduce or eliminate the pathogen.

Because of this combination of controls, the Agency is not requiring establishments to have a testing program for food contact surfaces. However, the establishments can test food contact surfaces for *L. monocytogenes*, or its indicator organisms, *Listeria* spp. or *Listeria-like* organisms periodically, to verify that their Sanitation SOP is effective. *L. monocytogenes* belongs to the *Listeria* group or genus of microorganisms, therefore a positive test for *Listeria* spp. or *Listeria-like* organisms would indicate the potential presence of the pathogen. If these specific indicator organisms test negative, this is indicative that *L. monocytogenes* is not present. Aerobic plate counts (APC), total plate counts (TPC), and coliforms are not appropriate indicator organisms for *L. monocytogenes*. Results from these tests do not indicate the presence or absence of the pathogen. Guidelines on sanitation procedures and food contact surface testing for *L.*

monocytogenes or its indicator organisms, *Listeria* spp. or *Listeria-like* organisms, are found in section D.

Alternative 2

An establishment that identifies its products in Alternative 2 must apply either a post lethality treatment or an antimicrobial agent or process that controls the growth of *L. monocytogenes*. The establishment must have the post-lethality treatment in its HACCP plan and the treatment must be validated according to § 417.4 as being effective in reducing or eliminating *L. monocytogenes* and should specify the log reduction achieved by the post-lethality treatment. The effectiveness of the post-lethality treatment must be verified by testing for *L. monocytogenes* and have the verification results available to FSIS personnel upon request. If an establishment has a product identified in Alternative 2 and uses a post lethality treatment to control *L. monocytogenes* in its product, it is not required to test food contact surfaces in the post-lethality environment. However, it can test food contact surfaces for *L. monocytogenes*, or its indicator organisms (*Listeria* spp. or *Listeria-like* organisms), or it may be subject to more frequent verification testing by FSIS.

An establishment in Alternative 2 that only uses an antimicrobial agent or process to control *L. monocytogenes* in its product must have the agent or process included in the establishment's HACCP plan, or sanitation SOP, or other prerequisite program. The establishment should have documentation in its HACCP plan, Sanitation SOP or other prerequisite program to demonstrate that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes*. The establishment should document the log levels of the pathogen that the antimicrobial agent or process can suppress and the length of time in days that the antimicrobial is effective. The establishment must validate and verify the effectiveness of its antimicrobial agent or process included in its HACCP plan in accordance with § 417.4.

If the antimicrobial agent or process is in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with § 416.14. If the control measures for *L. monocytogenes* are contained in a prerequisite program other than a Sanitation SOP, the establishment must ensure that the program is effective and does not cause the hazard analysis or the HACCP plan to be inadequate. The establishment should document its antimicrobial agent or process, its implementation and its verification results sufficiently in order to show that the HACCP plan is adequate in controlling the pathogen. The establishment must verify that the antimicrobials are effective by testing for *L. monocytogenes* and have the verification results whether from carrying out its HACCP plan, or Sanitation SOP, or other prerequisite program, available upon request to FSIS inspection personnel.

If an establishment's product is in Alternative 2 and uses an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes* in its product, it should maintain sanitation in the post-lethality environment in accordance with part § 416. The sanitation program must include testing for food contact surfaces in the post-lethality

environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or its indicator organisms (*Listeria* spp. or *Listeria-like* organisms). Studies on antimicrobials showed growth inhibition of *L. monocytogenes* if present at low levels of contamination during the shelf life of the RTE product. Antimicrobials were not shown to be effective at higher levels of contamination, so an effective sanitation program, which includes verification testing for food contact surfaces must be implemented at the same time that antimicrobials are used.

The sanitation program must provide for testing food contact surfaces in the post-lethality processing area to ensure that surfaces are sanitary and free of *L. monocytogenes* or its indicator organisms. It must include the frequency of testing and identify the size and location of the sample sites to be sampled. It should include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or its indicator organisms is maintained. In addition, the establishment must identify the conditions under which the establishment will implement hold-and-test procedures following a positive test for *L. monocytogenes* or its indicator organisms. The product will be subject to more frequent FSIS verification testing compared to a product using a post-lethality treatment to eliminate *L. monocytogenes*.

Alternative 3

A post-lethality exposed product that does not use a post-lethality treatment or an antimicrobial agent or process to control the growth of *L. monocytogenes* falls under Alternative 3. An establishment producing this product must control the pathogen in its post-lethality processing environment through the use of sanitation control measures, which may be incorporated in the establishment's HACCP plan, Sanitation SOP or prerequisite program. Because the establishment is not relying upon a post-lethality treatment or an antimicrobial agent or process to control *L. monocytogenes*, the product will be subject to frequent FSIS verification testing compared to the other alternatives. Examples of products in this alternative are fully cooked meat and poultry that are packaged and refrigerated such as hotdogs, deli meats, chicken nuggets, or chicken patties that did not receive any post-lethality treatment or antimicrobial agent or process.

For this alternative, the establishment must maintain sanitation in the post-lethality processing environment in accordance with part 416. The sanitation program must provide for testing food contact surfaces in the post-lethality processing area to ensure that surfaces are sanitary and free of *L. monocytogenes* or its indicator organisms. The testing program should include the frequency of testing, identify the size and location of the sample sites and include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or its indicator organisms is maintained. In addition, the establishment should identify the conditions under which the establishment will implement hold-and-test procedures following a positive test for *L. monocytogenes* or its indicator organisms on a food contact surface.

Moreover, an establishment that produces a deli product or a hotdog product must verify that the corrective actions that it takes with respect to sanitation after an initial positive

test for *L. monocytogenes* or its indicator organisms on a food contact surface in the post-lethality processing environment are effective. The corrective action must indicate steps that the establishment will take to clean and sanitize the suspected food contact surfaces to eliminate the contamination. The verification of the effectiveness of the corrective action can be shown by follow-up testing that includes a targeted test of the specific site on the food contact surface area that is the most likely source of contamination by the organism and other additional tests in the surrounding food contact surface area as necessary to ensure the effectiveness of the corrective actions. During this follow-up testing, if the establishment obtains a second positive test for *L. monocytogenes* or an indicator organism, the establishment must hold lots of product that may have become contaminated by contact with the food contact surface until the establishment corrects the sanitation problem indicated by the test result.

Further, in order to be able to release into commerce the lots of product that may have become contaminated with *L. monocytogenes* from the food contact surface, the establishment must sample and test the lots for *L. monocytogenes* using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes*. The ICMSF statistical sampling plan (International Commission on Microbiological Specifications for Foods) is an example of a plan that some establishments have used (Attachment 3).

If the product tests positive for *L. monocytogenes*, the sampled product lot is considered adulterated and must be withheld from commerce. The establishment may destroy the held product, or rework the held product using a process that is destructive of *L. monocytogenes*. The establishment must document the results of the testing and the disposition of the product. An example of a hold-and test scenario can be found in section E-VII.

An establishment with products in Alternative 3 is likely to be subject to more frequent verification testing by FSIS than an establishment with products in Alternative 1 or 2. This is because the products in Alternatives 1 and 2 are formulated and/or processed to reduce or eliminate *L. monocytogenes* or limit its growth in the RTE product and present a lower risk than products in Alternative 3 that do not have these interventions. Likewise, an establishment in Alternative 3 that produces deli meat or hotdog products is likely to be subject to more frequent verification testing than one that does not produce such products because deli and hotdog products were ranked as higher risks for *L. monocytogenes* contamination in the FDA/FSIS risk assessment.

For frequency of verification sampling, the Agency is expected to take into consideration the level of pathogen reduction achieved by the post-lethality treatment, the growth inhibition achieved by the antimicrobial agent or process during the shelf life of the product, and the rigor of the sanitation and testing program, i.e., whether the sanitation and testing program exceeds the compliance guidelines.

Enhanced level of effectiveness of the post-lethality treatment and the antimicrobial agent or process

Products that receive a post lethality treatment achieving at least 2.0 log reduction of *L. monocytogenes* may likely be sampled less frequently than products that receive a post-lethality treatment achieving <2.0 log reduction. Post lethality treatment achieving <1.0 log reduction will likely not be considered a post-lethality treatment for Alternatives 1 and 2 for purposes of the rule nor likely be eligible to apply for the labeling claim regarding enhanced protection from *L. monocytogenes* without supporting documentation that demonstrates this level of reduction provides a sufficient safety margin. In this case, the product may also be moved to a higher risk Alternative.

Likewise products receiving an antimicrobial agent or process that suppresses growth of *L. monocytogenes* such that there is 1.0 log or less increase during its shelf life may be expected to be verified less frequently than products receiving antimicrobial agent or process that suppresses the growth of *L. monocytogenes* by greater than 1.0 log increase during its shelf life. Use of an antimicrobial agent or process that allows more than 2.0 log growth increase during shelf life may not likely be considered an antimicrobial agent or process for Alternatives 1 and 2 for purposes of this rule unless there is supporting documentation that demonstrates that this level of growth provides a sufficient safety margin. In such cases, the product may be moved to a higher risk Alternative. In addition, products that allow greater than 1.0 log growth of the pathogen during its shelf life will not likely be eligible to apply for the labeling claim regarding enhanced protection from *L. monocytogenes*. In this case, the product may also be moved to a higher risk Alternative.

Labeling

Antimicrobial agents that are added to RTE products, either to the formulation or to the finished RTE product, and those that are included in the primary packaging material of RTE products are required to be included in the ingredients statement of the product label. In addition, establishments that use a post-lethality treatment or an antimicrobial validated to effectively eliminate or reduce *L. monocytogenes*, or suppress or limit its growth in the product can make claims or special statements on the labels of their products regarding the presence and purpose of use of the substances. The purpose of such claims is to inform consumers about measures taken by the processor to ensure the safety of the product and enable consumers to make informed purchase decisions. Such claims are voluntary, and may be of value to consumers especially those in groups most vulnerable to foodborne illness. Processors need to document their validation of these claims. An example of a statement that can be made is: "Potassium lactate added to prevent the growth of *L. monocytogenes*." All labeling claims and label changes to add such claims must be submitted for evaluation and approval to the FSIS Labeling and Consumer Protection Staff.

Estimates of Annual Production Volume

An establishment that produces post-lethality exposed RTE products shall provide FSIS with estimates of annual production volume and related information (such as the establishment's testing program) for the types of meat and poultry products processed

under Alternatives 1, 2, or 3. The establishment needs to provide the information at least annually, or more often, as determined by the Administrator. The Agency regards production volume as a more important risk factor than establishment size and therefore needs these data so that it can target its resources on higher volume operations in its verification program. FSIS will develop sampling frequencies for the establishments and the products based on these data. The Agency will make the sampling frequency available to the establishments so that they will have an indication of how the risk of *L. monocytogenes* is tied to verification sampling.

The form by which to collect the data will be available to establishments in paper or electronic formats. An electronic form for this purpose will be available to the establishments at all times after the rule becomes effective. A production volume sample form can be found in Attachemnt----.

B. Studies on Post-lethality Treatments

(Mention of trade marks or commercial names does not constitute endorsement by USDA)

I. Steam Pasteurization and Hot Water Pasteurization

Post processing contamination of RTE meat and poultry is mostly confined to the surface. Pasteurization by steam and hot water acts on the surface microbial contaminants by the action of heat. Studies on surface pasteurization using steam or hot water were shown to be effective in reducing this contamination.

Studies by Murphy et al. (2003a) showed that post-cook hot water pasteurization and steam pasteurization resulted in a 7 $\log_{10}$ reduction of *L. monocytogenes* in inoculated vacuum packaged fully cooked sliced chicken. The reduction was effective when single – packaged breast fillets, 227 g- package strips and 454 g-packaged strips were heat treated at 90 C in a continuous steam cooker or hot water cooker for 5, 25 and 35 minutes respectively. These investigators developed a model called ThermoPro that could predict the thermal lethality of pathogens in fully cooked meat and poultry products during post-cook in-package pasteurization (Murphy et al., 2001, 2003b, 2003c). The model was developed using L. innocua and verified for *L. monocytogenes*.

II. Pre-Package Pasteurization and Post-Package Surface Pasteurization

Pre-package surface pasteurization treatment of fully cooked meat removed from their packaging wrap and inoculated with *L. monocytogenes* resulted in a 1.25 to 3.5 log reduction with a treatment time of 60-120 sec at 475 to 750° F air temperature (Gande and Muriana, 2003). Surface pasteurization was applied on cooked whole and split roast beef, whole corned beef, and whole and formed ham using a radiant oven ("Infrared Grill", Unitherm FoodSystems). Pre-package pasteurization (60 sec) combined with post-package submerged water pasteurization using formed ham (60 or 90 sec), turkey bologna (45 or 60 sec), and roast beef (60 or 90 sec), resulted in a 3.2 to 3.9 log reduction for ham, 2.7-4.3 log reduction for bologna, or a 2.0-3.75 log reduction for roast beef. The

level of reduction varied depending on the method of inoculation, type of product used, treatment temperature, and residence time.

Muriana et al., (2002) used a stainless steel water bath (similar to the Unitherm commercial Aquaflow food processor) to submerge cooked RTE deli-style whole or formed turkey, ham and roast beef, removed from their package, inoculated with *L. monocytogenes* and vacuum packaged. Results show a 2-4 log decrease in the levels of L. monocyogenes in inoculated products post-cooked at 195-205° F for 2-10 min.

III. High Hydrostatic Pressure Processing

High pressure processing (HPP) is one of the new technologies used for food processing. This technology provides a means of ensuring food safety for those products that are difficult to be heat treated due to organoleptic effects. HPP was shown to inactivate pathogens without any thermal or chemical effects and at the same time preserve the quality of the product. Raghubeer and Ting (2003) evaluated the efficacy of high hydrostatic pressure processing in inactivating *L. monocytogenes* in retail-packaged samples of sliced ham, turkey and roast beef obtained from a manufacturer and repackaged in 25-g portions. Results show that an inoculum of about 10^4 *L. monocytogenes* cocktail in these 3 products and HPP treatment at 87,000 psi for 3 minutes showed no recovery of *L. monocytogenes* after 61 days of storage at 34° F. There were no pressure-injured cells detected. There were no adverse organoleptic effects detected on the 3 HPP treated products during the 61-day shelf life study. No signs of spoilage were seen on all 3 products after 61 days of storage, and for 100 days for ham and turkey. According to the investigators, the normal shelf life of these products is 30 days, so the HPP treatment extended the shelf life of the products.

C. Studies on the Use of Antimicrobial Agents

I. Addition of Lactates, Acetates, Diacetates to Meat Formulations

Studies have shown that lactic acid and acetic acid have significant antimicrobial activity in broth and food systems. Sodium and potassium salts of these acids, when added to processed meat formulations are also known to potentially inhibit pathogenic bacteria especially *L. monocytogenes*. These antimicrobials inhibit growth of pathogens by inhibiting their metabolic activities. Interest in these antimicrobials is in the growth inhibition of *L. monocytogenes* in post lethality exposed RTE meat and poultry products.

FSIS recently increased the permissible levels of sodium acetate as a flavor enhancer in meat and poultry products, and of sodium diacetate as a flavor enhancer and as an inhibitor of pathogen growth to 0.25 % (65 FR 3121-3123/2000). The rule also permitted the use of sodium lactate and potassium lactate in fully cooked meat, meat food products, poultry, and poultry food products, except for infant foods and formulas at levels of up to 4.8 % of total product formulation for the purpose of inhibiting the growth of certain pathogens. Approved antimicrobials for meat and poultry products can be found in 9 CFR 424.21. The addition of antimicrobials in the formulation must be included in the

ingredient statement of the label. Several studies used these antimicrobials to show their ability to inhibit growth of *L. monocytogenes* in different meat formulations.

Seman et al., (2002) developed a mathematical model capable of predicting the growth or stasis of *L. monocytogenes* in commercial cured meat products using a response surface method. The model can be used by manufacturers in the determination of the appropriate amounts of potassium lactate and sodium diacetate to be added to cured meat products that are organoleptically sensible and will not support the growth of *L. monocytogenes*. Thirty products were formulated by using a variety of raw material sources such as pork trimmings, trimmed turkey breast halves and four-muscle ham. Varying amounts of potassium lactate and sodium diacetate were added to the meat formulation and the meats were processed into different products. After chilling, the products were stripped of their casings, sliced into 25-g slices, placed into pouches, and inoculated with *L. monocytogenes* by applying to the surface of 100g of cured meat (four slices).

The results show that increasing amounts of potassium lactate syrup and sodium diacetate decreased the growth rate of *L. monocytogenes*, while increasing finished product moisture increased the growth rate. Sodium chloride content was not significant but was found to have a negative correlation to growth rate. The investigators provided a final regression equation predicting the growth of *L. monocytogenes* in cured RTE meat products stored at 4° C. The investigators used predictive model performance factors and a simple linear regression analysis to evaluate the model generated in this study. They verified the accuracy of the model by comparing with actual *L. monocytogenes* growth data from an independent challenge study conducted with four different commercial RTE meat products using similar storage conditions. Performance factors calculated and evaluated for control products (those not containing potassium lactate and sodium diacetate) indicated that on the average, the predicted growth of *L. monocytogenes* exceeded those of the observed values by about 24 %.

This study provided a useful model in determining the target amounts of potassium lactate and sodium acetate for cured meat product formulations to inhibit the growth of *L. monocytogenes*. The calculations would also require knowledge of the finished product sodium chloride and moisture contents. The investigators advised that this validated model is specific to the products designed for the study and the *L. monocytogenes* strains used. Testing of this model in other environments and with other *Listeria* spp., and to formulations that are outside the model's limits may result in different maximum growth rates. This study was used as the basis for the Opti.Form *Listeria* Control Model.

The Opti.Form Listeria Control Model (PURAC) is a unique tool to calculate the levels of lactate and diacetate required to retard the growth of *Listeria monocytogenes* in cured meat and poultry products. The model is based on the study detailed in the paper by Seman et al, 2002, above. The model, which is available on CD-Rom includes:

- instructions on how to use the model
- explanation on the development of the model
- information on the anti-microbial effect of lactate and diacetate
- lactates and diacetates and use of these products

- regulations and labeling
- literature references

To receive a free copy of the model on CD-Rom, call: 888-899 8229, E-mail pam@purac.com

Bedie et al., (2001) evaluated the use of antimicrobials, included in frankfurter formulations, on *L. monocytogenes* populations during refrigerated storage. Fully cooked and cooled frankfurters were inoculated with 10^3 to 10^4 CFU /cm^2 of *L. monocytogenes* after peeling and before vacuum packaging. Samples were stored at 4° C for up to 120 days and sampled for testing on assigned days. Results are as follows:

ANTIMICROBIAL	LEVEL (%)	*L. MONOCYTOGENES* GROWTH INHIBITION
Sodium lactate	3	70 days no pathogen growth
Sodium diacetate	0.25	50 days no pathogen growth
Sodium acetate	0.25, 0.50	20 days no pathogen growth
Sodium lactate	6	120 days no growth and reduced pathogen growth
Sodium diacetate	0.5	120 days no growth and reduced pathogen growth
Inoc. Control	0.0	Increased to 6 logs in 20 days

No pathogen growth refers to no increase in the number of inoculated L.monocytogenes cells (bacteriostatic); while reduced pathogen growth refers to a decrease in the number of inoculated *L. monocytogenes* cells (bactericidal) in the product. In this study, tables showed the reduction varied with storage days, but was up to 1.0 log on some days. Antimicrobials were found to have no effect on pH except for sodium diacetate at 0.5 % which reduced the initial pH. Using the formulations and conditions in the study, establishments can add 3 % sodium lactate in the frankfurter formulation and obtain no growth of *L. monocytogenes* up to 70 days at refrigerated storage of 4° C. If the lethality treatment is adequate to eliminate *L. monocytogenes*, then the only probable source of *L. monocytogenes* would be from exposure of the product during peeling and repackaging. However, the establishment's sanitation program may keep the numbers to a very low level, and 3 % sodium lactate included in the formulation would inhibit the growth of *L. monocytogenes* during the product's refrigerated shelf life. Levels of sodium lactate at 6.0 % and sodium diacetate at 0.5 % showed a reduction of the pathogens, however these levels are above the permitted levels. Note: Sodium acetate is approved as a flavor enhancer, not as an antimicrobial agent.

This study by Samelis et al., (2002) used similar treatments, processing and inoculation procedures and frankfurter formulations as the previous study described above. However, in this study combinations of antimicrobials were used, and in combination with hot water treatment. Hot water treatment involved immersion of frankfurters, with two product links in a package to 75 or 80° C for 60 s. Storage at 4° C shows:

TREATMENT	LEVELS	*L. MONOCYTOGENES* GROWTH

	(%)	INHIBITION
Sodium lactate	1.8	35-50 days no growth
Sodium lactate + sodium acetate	1.8 0.25	120 days no growth; 35-50 days growth reduction
Sodium lactate + Sodium diacetate	1.8 0.25	120 days no growth; 35-50 days growth reduction
Sodium lactate + Glucuno-delta-lactone	1.8 0.25	120 days no growth, 35-50 days growth reduction
Hot water treatment (80° C, 60 s) + Sodium lactate	1.8	Inoc. population reduced by 0.4-0.9 log CFU/cm^2, and 50-70 days growth reduction by 1.1-1.4 CFU/ cm^2
Hot water treatment (80° C, 60 s)		Increase in growth to about 6-8 logs in 50 days
Inoculated Control, no treatment		Increase in growth to about 6 logs in 20 days and 8 logs thereafter up to 120 days

Note: Sodium lactate was used as a 3 % of a 60 % (wt/wt) commercial solution. Glucuno-delta lactone is approved as an acidifier, and a curing accelerator, but not as antimicrobial. Sodium acetate is approved as a flavor enhancer, not as an antimicrobial agent.

Glass et al., (2002) evaluated sodium lactate and sodium diacetate on wieners and cooked bratwurst containing both beef and pork supplied by a commercial manufacturer. Antimicrobial solutions used were sodium lactate and sodium diacetate singly or in combination at varying concentration. Wieners were repackaged in gas-impermeable pouches, then surface-inoculated with *L. monocytogenes* mixture on multiple areas of the surface of each link. Packages were vacuum-sealed and stored at 4.5° C for up to 60 days. Two types of cooked bratwurst from a commercial manufacturer were evaluated: bratwurst that was cured and naturally smoked and bratwurst that was uncured and unsmoked. Bratwurst was stored at 3 or 7° C for up to 84 days.
The surface treatment consisting of dipping wieners into solutions containing up to 6 % lactate and up to 3 % diacetate for 5 s did not delay pathogen growth, indicating that dipping wieners in the lactate/diacetate solutions is not an efficient way to apply the antimicrobials. However, the inclusion of lactates and diacetates in the formulation was found effective in inhibiting growth of *L. monocytogenes*. Results are as follows:

PRODUCT	Sodium Lactate (%)	Sodium diacetate (%)	*L. monocytogenes* levels (CFU/pkg)
Bratwurst uncured, unsmoked	3.4	0.1	Growth delayed for 4-12 weeks at 7 and 3° C storage, respectively.
	2.0	0.0	Growth delayed for 1-2 weeks at 7 and 3°C
Bratwurst	3.4	0.1	Growth inhibited for 12 weeks at 7 and

cured, smoked	0.0	0.0	3°C Growth up to 1 log after 4 weeks at 7 and 3° C
Wieners	3.0 1.0	0.0 0.1	Growth inhibited for 60 days at 4.5° C Growth inhibited for 60 days at 4.5° C

Study by (Porto et al., 2002) used freshly processed peeled frankfurters in vacuum sealed packages obtained from a commercial manufacturer. Two formulations of links were used in the study: one with added 2 or 3 % potassium lactate and the other without added potassium lactate. Frankfurters were aseptically removed from their original package, repackaged, and inoculated with a mixture of *L. monocytogenes*. The packages were vacuum-sealed to 95 kPa and incubated at 4 and 10° C.
Results show that addition of 2 % or 3 % potassium lactate in frankfurters can appreciably enhance safety by inhibiting or delaying the growth of *L. monocytogenes* during storage at refrigeration or abused temperatures. The viability of the pathogen was influenced by pH, and the levels of lactate added, but not by the presence of indigenous lactic acid bacteria.

Potassium lactate (%)	Inoculum CFU/pkg	Storage temp °C)	Days Storage	*L. monocytogenes* levels (CFU/package)
2.0	20	4	90	Remained at about 1.6 log
3.0	20	4	90	Remained at about 1.4 log
3.0	500	4	90	Remained at about 2.4 log
0.0	20	4	90	Increased to about 4.6 log
0.0	500	4	90	Increased to about 5.0 log
2.0	20	10	60	Remained at about 1.4 log
3.0	20	10	60	Remained at about 1.1 log
0.0	20	10	60	Increased to about 6.5 after 28 days, declined to about 5.0 after 60 days
3.0	500	10	60	Remained at about 2.4
0.0	500	20	60	Increased to about 6.6 log after 40 days and declined to about 5.5 log after 60 days

II. Growth Inhibitor Packaging

Growth inhibitor packaging is an intervention, which delivers an active antibacterial agent to the surface of an encased sausage product. By incorporating this special coating onto the internal surface of cellulose casings, the antilisterial treatment is transferred to the surface of the processed meat/sausage during thermal processing. Upon removal of the casing, the treatment remains active on the meat surface, providing effective protection against inadvertent Listeria contamination during subsequent peeling and packaging processes. Growth inhibitor packaging used in conjunction with functional HACCP and Good Manufacturing Practices provides the industry with one more tool in

their intervention strategy to control the risk of pathogen contamination in ready-to-eat meat and poultry products.

Studies on meat formulations for hot dogs using NOJAX® AL™ (Viskase) showed that use of the casings provide a lethality hurdle to the growth of *Listeria monocytogenes*, not just an inhibitory effect. The lethality impact is delivered within the first hours/days of the sausage/hot dog package life. This impact is dependent on many variables but is generally in the range of 1 – 2 log kill of *L. monocytogenes* at high levels of inoculation. This performance has been observed in challenge studies conducted on hot dogs drawn from commercial full-scale trials at a number of commercial processing plants. In high inoculation trials, NOJAX AL has been combined with conventional growth inhibiting additives, and as expected, the lethality impact is obtained and then maintained throughout the product life cycle. In these same trials, without growth inhibiting additives, this casing produces lethality but in several weeks the remaining *L. monocytogenes* begin to grow.

NOJAX AL is available in the U.S. having approval by both FDA and USDA for its key component, nisin. This GRAS component must be included in the ingredient statement via a label change request to the FSIS Labeling and Consumer Protection Staff. Because this is a naturally derived polypeptide, there are storage and use-by criteria that will have to be adhered to by the user for maximum benefit. Casing shelf-life is about 60-90days with a not to exceed 85° F.

This technology can be applied to most hot dogs and sausages that are encased in cellulose casing. This casing intervention can be used in any instance were casing is used as a mold for processed meat and poultry during thermal processing. This would include cellulose, plastic, and possibly natural casing. As part of a manufacturer's decision to use this technology, benefits are: 1) no capital costs or new equipment; 2) no change in processing steps, plant reconfigurations or introduction of process bottlenecks—essentially processor transparent in all aspects of use except casing storage requirements; 3) no impact on flavor, texture, or package appearance, and 4) minor labeling change to ingredient statement
Since this is a surface treatment, cost will be proportional to the surface to volume ratio of the product: the larger the sausage diameter, the lower the cost per pound. In general, economic analyses put the cost of this lethality intervention at about 2-3 cents per pound of finished product, with a mid-range target price of 2.5 cents per pound for a traditional 10-to-the-pound retail pack of hot dogs.

Janes et al., (2002) investigated the effect of nisin added to zein film coatings (Z) coated onto cooked ready-to-eat chicken against *L. monocytogenes*. Cooked chicken samples inoculated with *L. monocytogenes* were dipped into Z dissolved in propylene glycol or ethanol, with or without added nisin (1,000 IU/g) and/or 1 % calcium propionate and stored at 4 C or 8 C for 24 days. After 16 d at 4 C, *L. monocytogenes* was suppressed by 4.5 to 5 log CFU/g with zein film coatings with nisin. The most effective treatment in the study for controlling *L. monocytogenes* on the surface of ready-to-eat chicken was using edible zein film coatings containing nisin at a storage temperature of 4°C.

The use of film coatings in a processing plant would be to fully process the meat products then coat them with the films. Coating can be done by spraying or dipping the processed meat products and then allowing them to dry. Zein coatings on the meat products can be dried by circulating air around the meat product using a fan. Finally, the dried coated meat products can be packaged with the usual plastic film material and refrigerated. Nisin, for this purpose, is presently not approved in the USA for use on ready-to-eat meat and poultry products, and this study has not been tested in commercial poultry processing conditions.

Some general observations from the published studies on antimicrobials:

- Lactates, acetates and diacetates were found more effective in inhibiting growth of *L. monocytogenes* when used in combination than when used singly.
- These antimicrobials were found more effective when used to the maximum allowable concentration. However, higher concentrations of antimicrobials used in the formulation may affect the sensory qualities of the product, such as flavor and texture, which would necessitate sensory evaluation of treated products.
- When used in combination, the amount needed to inhibit growth may be reduced.
- These antimicrobials were found to have listeriostatic activity more than listericidal activity, i.e. they prevent growth of the pathogen more than reduce the number of cells of the pathogen, and therefore may not be effective against gross contamination of a product. The establishment's sanitation program should control gross contamination of the processing environment and equipment. Addition of antimicrobials would be effective only as part of the overall HACCP strategy.
- Including these antimicrobials in the formulation was found to be more effective in inhibiting listerial growth than dipping products in solutions of antimicrobials.
- The antimicrobial activity of lactates and diacetates when used singly or in combination is affected by the level of contamination of the meat product surface, and processing factors such as pH, moisture, water activity, fat, nitrite, salt content, time and temperature of storage, and packaging atmosphere.
- Application of the treatments used in these studies is limited to the formulations, products and treatments used in the studies. Applying these studies to other products and formulations may result in different rates of growth inhibition. Therefore the effectiveness of the antimicrobials used in these studies must be verified by the establishment for other processed meat products and other storage temperatures.
- Antimicrobials used in the formulation must have an effective antilisterial activity throughout the commercial shelf life of the product. Currently the targeted commercial shelf life of refrigerated cooked meat products in the U.S.A. is 75 to 90 days.
- Using post-packaging thermal treatments in addition to antimicrobials was found to increase the total antilisterial effects of the antimicrobials.
- These antimicrobials were found to be more effective in smoked products formulated with sodium nitrite, or in products stored at strict refrigeration temperatures.

- Use of these antimicrobials may be a cost effective antilisterial method that very small establishments can use.

D. Sanitation Guidelines for *Listeria monocytogenes*

Control of *L. monocytogenes* is a challenge to a processing plant's sanitation program. The pathogen can grow in a damp environment, attach to surfaces that come into contact with raw or finished product, establish a niche and form biofilms. The sanitation program should include cleaning and sanitizing procedures that have been proven effective for the particular operation, separation of raw and RTE processing areas, traffic control, employee hygiene, and equipment flow and design among others.

Proper and effective sanitation involves both cleaning and sanitizing, and verifying that the cleaning and sanitizing were effective. This involves developing and implementing written sanitation standard operating procedures (Sanitation SOP's). Sanitation SOP's could be viewed as the first step to designing a total system, including the HACCP plan, that will prevent, eliminate, or reduce the likelihood of pathogenic bacteria from entering and harboring in the plant environment. The Sanitation SOP's as described in 9 CFR 416.12 through 416.16, give detailed mandatory requirements for developing and implementing the sanitation program, while § 416.17 describes how FSIS will verify that each establishment is meeting the Sanitation SOP regulations. In brief, the regulations require the following:

- **Development of Sanitation SOP's (416.12)** – Each establishment shall develop a written Sanitation SOP that describes all sanitation procedures to be performed each day, before and during operations with specific frequencies of each procedure and the responsible person for each task. It must also describe the cleaning process for all food contact surfaces, utensils, and equipment used to process your product(s). This document must be signed and dated by either the person responsible for the overall sanitation operations or a higher level employee in the establishment once it is implemented, and when any changes are made to the Sanitation SOP's.
- **Implementation of SOP's (416.13)** – All preoperational procedures identified in the Sanitation SOP shall be done daily, before processing operations start. Each procedure must be performed at the specified frequency and they must be monitored daily.
- **Maintenance of Sanitation SOP's (416.14)** – Each establishment shall routinely determine if the written Sanitation SOP is still effective in preventing direct product contamination and adulteration. If the Sanitation SOP is determined not to be effective because of changes in equipment, utensils, facility, operations, or personnel, changes in the procedures must be made to reflect changes
- **Corrective Action (416.15)** – The appropriate corrective action(s) shall be taken when it has been determined by FSIS or by an establishment employee that the

written Sanitation SOP has failed to prevent direct product contamination or adulteration of your product(s).

- **Recordkeeping Requirements (416.16)** – Daily records shall be maintained that describe how the sanitation activities were implemented and monitored, and all corrective actions taken; these records must initialed and dated. Both computer records and paper records are appropriate; however, additional controls may be needed to ensure the integrity of the electronic data.
- **Agency Verification (416.17)** – FSIS will verify the effectiveness and adequacy of the written Sanitation SOP's to ensure that they meet all of the regulatory requirements. This will be done by reviewing all records, direct observations, and microbial testing as deemed necessary.

I. General Procedures

An example of equipment and processing room cleaning using eight steps is outlined below. Cleaning should be increased and intensified during periods of construction.

1. Remove waste material. Dry clean equipment, conveyor belts, tables, floors to remove meat particles and other solid debris. Some equipment such as slicers and dicers need to be disassembled so that parts can be cleaned thoroughly. Equipment may need to be cleaned and sanitized again after re-assembly.
2. Wash and rinse floor.
3. Pre-rinse equipment (rinse in same direction as product flow). Pre-rinse with warm or cold water – less than 140°F (hot water may coagulate proteins or "set soils").
4. Clean and scrub equipment. Always at least use the minimum contact time for the detergent/foam. Written instructions should be provided on the location of possible niches and the cleaning method to use. CAUTION: Live steam for cleaning is not acceptable at this step since it may bake organic matter on the equipment.
5. Rinse equipment (rinse in same direction as product flow).
6. Visually inspect equipment to identify minute pieces of meat and biological residues (repeat steps 3 and 4 if not clean visually or by testing such as with ATP bioluminescence).
7. Sanitize floor and then equipment to avoid contaminating equipment with aerosols from floor cleaning. Care should be taken in using high pressure hoses in cleaning the floor so that water won't splash on the already cleaned equipment. Use hot water, at least 180°F, for about 10 seconds to sanitize equipment. Sanitizers (e.g., chlorine, quaternary ammonia, etc.) may be more effective than steam for *L. monocytogenes* control. If steam heating equipment in an oven or tarp, the target internal temperature is 160° F and hold for 20-30 min. Portable high-pressure, low volume cleaning equipment (131°F (55°C) with 20-85 kg/cm^2 pressure and 6- 16 liters/minute) can be used.
8. Remove excess moisture. This can be done most safely and efficiently by air drying. Reduced relative humidity can speed the process. Avoid any possible

cross-contamination from aerosol or splash if a method other than air drying (e.g., using a squeegee or towel) is used. If cross-contamination is suspected, repeat steps 4 – 7.

II. Determining the Effectiveness of Sanitation Standard Operating Procedures (Sanitation SOPs)

The establishment should determine if the cleaning and sanitizing procedures used is effective by visual examination or testing or both.

1) Visual inspection of the equipment and environment. Visual inspection is the minimum means of determining the effectiveness of the sanitation (SOPs). It can only detect observable contamination.

a. Visually verify that no meat or product residue is on the equipment, especially those food contact surfaces and areas that may serve as niches for bacteria, before the start of operation.
b. Record the results of the visual inspection.
c. If any residue is noted, corrective action should be taken and recorded.
d. The monitoring record should be designed to show any trends of insanitary conditions. For example, if corrective action had to be taken on the first two days of operation for more than a week, this indicates a possible problem with cleaning and would have to be investigated to determine the source of the problem (e.g., improperly trained crew on those days, types of products processed).
e. Visually verify that no meat or product residue is on the equipment, especially those food contact surfaces and areas that may serve as niches for bacteria, after post-processing cleanup.

2) Visual inspection and use of ATP bioluminescence testing. Visual verification combined with ATP testing can determine both observable contamination and contamination from bacteria and meat/poultry residues that may not be visually detectable. The combined methods are more effective in determining the effectiveness of the sanitation SOP.

a. The ATP test indicates the presence of both bacteria and meat or poultry residues and can be used to verify that no meat or poultry residue is on the equipment, esp. those food contact surfaces and areas that may serve as niches for bacteria, before the start of operation. The ATP test is a rapid test and results are available immediately.
b. Record the results of the ATP test and visual inspection.
c. If any residue is noted or observed visually or the ATP test indicates an insanitary condition, corrective action should be taken and recorded.
d. The monitoring record should be designed to show any trends of insanitary conditions. For example, if corrective action had to be taken on the first two days of operation for more than a week, this indicates a possible problem with cleaning and would have to be investigated to determine the source of the problem (e.g., improperly trained crew on those days, types of products processed).

3) Visual inspection and total plate counts (TPC). Visual verification combined with TPC can determine both observable contamination and the level of bacterial contamination. Since TPC results are available in about 24 hours, and cannot be obtained at the time of inspection, its value lies in the measurement of the level of contamination. The level of contamination may assist the establishment in determining the source of contamination and the effectiveness of the sanitation SOP.

a. Visually verify that no meat or product residue is on the equipment, esp. those food contact surfaces and areas that may serve as niches for bacteria, before the start of operation.
b. Use swabs or RODAC plates for sampling food contact surfaces, non-food contact surfaces (e.g., push-button on/off switches for the conveyor belt), and the processing environment.
c. Record the results of the visual inspection.
d. If any residue is noted, corrective action should be taken and recorded.
e. Record the TPC when analysis is complete.
f. The monitoring record should be designed to show any trends of insanitary conditions as determined by visual inspection or TPC. For example, if corrective action had to be taken on the first two days of operation for more than a week, this indicates a possible problem with cleaning and would have to be investigated to determine the source of the problem (e.g., improperly trained crew on those days, types of products processed).
g. Visually verify that no meat or product residue is on the equipment, especially those food contact surfaces and areas that may serve as niches for bacteria, again after post-processing cleanup.

III. Traffic Control

Controlling the movement of personnel and raw and finished products will help prevent cross-contamination of finished products by raw materials and personnel. The following are steps that can be taken for traffic control:

1. Establish traffic patterns to eliminate movement of personnel, meat containers, meat, ingredients, pallets and refuse containers between raw and finished product areas.
2. Control traffic into and within the RTE areas
   a. If possible, use air locks between raw and RTE areas.
   b. Clean, dry floors are preferable to foot baths at the point of entry because effective concentrations of disinfectant are difficult to maintain and may become a source of contamination.
   c. If foot baths are used:
      i) Wear rubber or other non-porous boots.
      ii) Maintain them properly,
      iii) Solutions should contain stronger concentrations of sanitizer than normally used on equipment

(1) For example, 200 ppm iodophor, 400-800 ppm quaternary ammonia compound).
(2) CAUTION: Chlorine is not recommended as it is too quickly inactivated esp. if cleated boots are used. The accumulation of biological material adhering to the cleats inactivate (or reduce) the bioavailability of chlorine and make it less effective. Monitor and maintain its strength if used.

iv) Use a minimum depth of 2 inches.

d. Use foam disinfectant spray on floor, since people or rolling stock enter the room.

3. Employees should not work in both raw and RTE areas, if possible. If they must work in both areas, they must change outer and other soiled clothing, wash and sanitize hands, and clean and sanitize footwear.
   a. Use different color smocks or helmets for raw and RTE areas so the workers and garments in the raw and RTE areas are readily distinguishable.
   b. Remove outer garments (e.g., smocks) when leaving RTE areas.
4. Do not allow employees who clean utensils and equipment for raw materials to clean RTE utensils and equipment, if possible. If not possible, there should be a time separation when utensils for raw processing/handling are cleaned after RTE. The tools to clean utensils and equipment for raw materials must be different than those used to clean RTE utensils and equipment. In either case, the intent is to prevent cross contamination of finished product.
5. Do not permit maintenance employees in RTE areas during operations if possible, primarily because they may cause direct product contamination or adulteration if they touch or lay their "dirty" equipment hands onto food contact surfaces. If not possible:
   a. Consider the need to cease operations until a full cleaning and sanitizing is done, or,
   b. Maintenance personnel must change outer clothing and any other soiled clothing, use separate tools for raw and RTE areas (or wash and sanitize tools and hands prior to entering RTE areas) and wear only freshly cleaned/sanitized footwear in such areas.
6. Use separate equipment, maintenance tools and utensils for the RTE and raw areas. If not possible, there should be a time separation between raw processing/handling and RTE processing in order prevent cross contamination of finished product.
7. Pallets can serve as a source of cross-contamination – pallets for raw materials should not be used in RTE areas or used for finished product.
8. Drains from the "dirty" or "raw" side should not be connected to those on the "clean" or "cooked" side.

IV. Employee Hygiene

Employee hygiene should be the responsibility of both the individual and management. The employee should be responsible for preventing contamination of food products and the management should be responsible for ensuring the employee is properly trained and maintains good practices.

Employee responsibilities and actions should include:

1. Use a 20 second hand wash, allowing the soap suds to be in contact with the hands for this period of time, after using restroom facilities.
2. Wash hands before entering the work area, when leaving work area, and before handling product.
3. If gloves are worn:
   a. Gloves that handle RTE product must be disposable.
   b. Dispose immediately and replace if anything other than product and food contact surface is touched.
   c. Dispose of gloves when leaving the processing line.
4. Remove outer clothing when leaving RTE areas.
5. Do not wear RTE clothing inside restrooms or cafeterias.
6. Do not store soiled garments in lockers.
7. Do not eat in the locker room or store food in lockers because food may attract insects and vermin.
8. Do not store operator hand tools in personal lockers. This equipment must remain in the RTE area at all times.

Management responsibilities should include:

1. Providing hand washing facilities at proper locations.
2. Ensuring the employee receives proper hygiene instruction before starting – use of hand soaps and sanitizers, no-touch dispensing systems, and boot and doorway sanitizing systems.
3. Developing a system for monitoring employee hygiene practices.
4. Developing a system for tracking the training, tests taken, and certification.
5. Retraining employees before placing back into production if they are absent from the job or have failed to follow acceptable hygiene practices. This will help ensure that the employees are following current, acceptable hygiene habits.

V. Sanitizers

Cleaning and sanitizing are vital to any effective sanitation program. Thorough cleaning should be followed by sanitizing. Generally, the cleaning step is to remove all waste materials and soils, and the sanitizing step is to destroy all microorganisms. Careful consideration should be given to selecting both cleaning and sanitizing solutions. It is important to use solutions that are compatible with the equipment materials, such as stainless steel or heavy plastics, and solutions that are effective in destroying the type of bacteria commonly associated with the type of products produced in the establishment.

The concentration and application processes for all sanitizers approved for use in meat and poultry establishments are referenced in Title 21 Code of Federal Regulations (21 CFR), Part 178.1010. All cleaners and sanitizers commercially available should have at the minimum, the following information either on the label or available on a specification sheet that must accompany the product:

- ✓ Product Description
- ✓ To Use – Instructions on how to use the product

- ✓ Properties
- ✓ Safety Information

Additional information that is sometimes available includes:

- ✓ Benefits
- ✓ Quality Assurance Statements

Some manufacturers provide labeling in both English and Spanish, which makes the products more user friendly in various environments. At least one manufacturer, Ecolab Inc., also has commercially available color coded products that are easy to associate with a particular cleaning or sanitizing task.

Krysinski, L.J., (1992) evaluated the ability of chemical cleaning and sanitizing compounds to remove and/or inactivate surface adherent *Listeria monocytogenes* from stainless steel and plastic conveyor belts.
With respect to the sanitizers, the study showed that resistance of attached cells followed in descending order: polyester/polyurethane, and stainless steel. For the stainless steel, all of the sanitizers were effective in inactivating the adherent *Listeria monocytogenes* except chlorine and iodophor. None of the biocides were effective in sanitizing the surface of the polyester/polyurethane. The most effective sanitizers in these evaluations were acidic quaternary ammonia, peracetic acid, and chlorine dioxide. The cleaning agents used were effective in removing the attached organisms for the stainless steel but not effective when used on the polyester/polyurethane chips. When the cleaning agents were followed by a sanitizer, reductions in the microbial load were observed. The study concluded that generally, acidic quaternary ammonia, chlorine dioxide, and peractetic acid were the most effective biocides on attached organisms, less effective were the mixed halogens and acid anionics, and the least effective were chlorine, iodophors, and neutral quaternary ammonium compounds.

VI. Sources and Control of *Listeria monocytogenes* Contamination

Listeria monocytogenes may be constantly introduced into the processing environment by inadvertent actions of plant employees or other entry vectors. It may be introduced by incoming raw product, processing environment or by employees. The following are steps that should be taken to prevent contamination of product with *L. monocytogenes* after cooking:

1. Verify that cooking or other control measures will eliminate *L. monocytogenes*. Scientists believe that most meat products implicated in human listeriosis are contaminated with *L. monocytogenes* after these measures are applied. Undercooking product or other inadequate or improperly verified lethality treatments may introduce *L. monocytogenes* to food contact surfaces or the environment after cooking and before packaging.

2. Prevent contamination of food contact surfaces and prevent the formation and growth of *L. monocytogenes* in a niche, especially in areas after the lethality step. A niche is a harborage site within the plant that provides an ideal place for *L. monocytogenes* to establish and multiply. Factors involved in the formation of niches include equipment design, operational conditions that move product debris into uncleanable locations, mid-shift cleanup, high pressure during cleaning, and product characteristics that require excessive rinsing. Certain strains can become established in a processing environment for months or years. *L. monocytogenes* can be spread from these sites and re-contaminate food or food contact surfaces between the lethality step and packaging.

Examples of reservoirs and harborages of *L. monocytogenes* in RTE processing environment
Hollow rollers on conveyors
On-off valves and switches
Worn or cracked rubber seals around doors
Vacuum/air pressure pumps, lines, hoses
Cracked tubular rods on equipment
Air filters
Drains
Condensate from refrigeration unit
Floors
Standing water
Open or gulley drains
Ceilings and over head pipes
Overhead rails and trolleys
Chiller and passageway walls and doors
Chiller shelving
Roller guards
Door handles
Boots
Ice makers
Saturated insulation (wet or moldy)
Trolley and forklifts
Compressed air in-line air filters
Trash cans
Cracked hoses
Wet, rusting or hollow framework
Walls that are cracked, pitted, or covered with inadequately sealed surface panels
Maintenance and cleaning tools
Space between close fitting metal-to-plastic parts
Space between close fitting metal-to-metal parts

3. Examine routes taken by products from heat treatment, or other control to eliminate *L. monocytogenes*, to final packaging.

Typical sites of *L. monocytogenes* contamination
Filling or packaging equipment
Solutions used in chilling food
Peelers, slicers, shredders, blenders, brine chill, casing removal system, scales, or other equipment used after heating and before packaging
Spiral or blast freezers
Conveyors
Bins, tubs, or other containers used to hold food for further processing

4. Frequently clean sites known to support *L. monocytogenes* using effective cleaning procedures. The following is a recommended frequency for cleaning and sanitizing processing equipment and the plant environment:

    a. Daily
        i. All processing equipment
        ii. Floors and drains
        iii. Waste containers
        iv. Storage areas
    b. Weekly
        i. Walls
    c. Weekly/monthly
        i. Condensate drip
        ii. Coolers
    d. Semiannually
        i. Freezers

5. Validate that the cleaning and sanitizing procedures are effective.

6. Maintain equipment and repair parts or machinery in a manner to prevent food deposits that are not easily removed with normal cleaning.

7. Implement a microbial sampling program to monitor and detect sources of *L. monocytogenes* in the environment. Environmental testing is more effective then product testing alone to monitor and detect Listeria in the environment.

8. Design a sampling scheme to locate a niche before *L. monocytogenes* becomes established.

    a. Use statistically designed sampling plans based on probability, such as those described in ICMSF 7 or Military Standards (MIL-STD-105E), or

    b. Determine the physical area to sample. Use prior experience with processing conditions and observation of cleaning and sanitizing procedures and equipment to determine the most likely source of

contamination. For example, the use of high water pressure during cleaning may embed *L. monocytogenes* into parts of the equipment that are hard to clean effectively. The cleaning and sanitizing procedures also should be monitored to assure that the established procedures are being followed. All surfaces of processing equipment should be sampled but with a bias toward those areas identified as possibly problematic.

c. Review at least the last month of results to determine trends or to revise sampling scheme.

d. When a problem area is detected, take corrective action on the affected processing line as opposed to adjacent lines in the area. Target the area corresponding to the line associated with the findings for cleaning. Contamination is usually line specific unless a vector in the system is present (e.g., an employee contaminates multiple sites; a common surface prior to splitting the lines is contaminated).

Equipment Design

Selecting the appropriate equipment (e.g., easily dismantled for cleaning, durability) enhances cleaning operations and helps to control *L. monocytogenes* in the plant environment. The following are recommended steps to take when selecting equipment:

1. If possible, develop a team (persons from Quality Assurance, Sanitation, Maintenance, and Production) to evaluate equipment before it is purchased or set specific requirements for plant equipment. The equipment should be easy to clean and sanitize and not have potential *L. monocytogenes* harborage sites, such as hollow rollers.

2. Have the equipment reviewed by a third-party expert if possible.

3. Select equipment designed to minimize sites on the exterior or interior where *L. monocytogenes* can grow.

4. Select equipment designed to enhance cleaning.

    a. All areas and parts should be accessible for manual cleaning and inspection or be readily disassembled.

        i. Closed conveyor designs are more difficult to clean. Equipment on the processing line should be as easy to clean as possible.

        ii. Avoid hollow conveyor rollers and hollow framing. If hollow material is used, have a continuous weld seal instead of caulk.

iii. Select food contact surfaces that are inert, smooth and non-porous.

b. Equipment should be self-draining or self-emptying.

5. Equipment evaluation

a. Thoroughly clean and sanitize equipment prior to using in production. Pathogens can live on surfaces that appear visually clean.
b. Operate the equipment for 90 days, then,
c. Disassemble to normal daily level, then
d. Evaluate visually and microbiologically as the equipment is completely disassembled.

6. Maintain equipment and machinery by adopting regular maintenance schedules.

a. Damaged, pitted, corroded, and cracked equipment should be repaired or replaced.

i. Repair parts or machinery in a manner to prevent food deposits that are not easily removed with normal cleaning.

ii. Use separate tools for RTE equipment only. Sanitize them before and after each use.

b. If compressed air is used, maintain and replace in-line filters regularly.

c. Use lubricants that contain listericidal additives such as sodium benzoate. *L. monocytogenes* can grow in lubricants that are contaminated with food particles.
d. Use the appropriate cleaners and sanitizers on surfaces or equipment.

VII. Verifying the Effectiveness of the Sanitation Program (Testing for *Listeria monocytogenes*, *Listeria* spp. or *Listeria*-like organisms)

Establishments can verify the effectiveness of their sanitation program by testing food contact surfaces (FCS) and other relevant environmental surfaces. This section includes a) recommended testing of food contact surfaces to verify the effectiveness of the sanitation program for each alternative from 9 CFR 430, b) a guide to testing for *Listeria* spp or *Listeria*-like organisms, c) an example of a hold-and-test scenario, and d) an example of a Sentinel Site Program.

A. Food Contact Surface and Environmental Testing

The sampling frequencies for food contact surface (FCS) testing suggested below are recommended minimum frequencies. The sampling frequencies increase from

Alternative 1 to Alternative 3 because the control program for *L. monocytogenes* decreases in intensity and effectiveness from Alternative 1 to 3. These frequencies should be increased if there is construction, change in the HACCP plan, roof leaks, or other events that could change or increase the probability of product contamination. Samples should be taken at least 3 hours after the start of operation or an appropriate time period after all parts of the food handling system are operational because the equipment has to be operational for seeding to occur.

Generally, no more than 5 samples may be composited because when samples are composited, it becomes more difficult to trace the source of contamination. In addition, it is recommended that like surfaces should be composited (e.g., food contact surfaces with other food contact surfaces, etc.). The sample locations for the composite sample should be noted to assist in determining the site of contamination to facilitate follow-up testing in case a positive is obtained. Environmental samples other than food contact surface samples should be sampled by the establishment. This will also assist the establishment in locating potential sources of contamination.

The establishment is encouraged to hold all products being tested until the test results are received. This will prevent exposure of the consumer to a potential food hazard. Retaining the product being tested also will eliminate the cost of a recall to the establishment.

1. Alternative 1 – Use of a post-lethality treatment and an antimicrobial agent or process that limits growth of *L. monocytogenes*.
   i) Conduct tests of food contact surfaces for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms at least twice a year. This low frequency of testing is recommended because the post-lethality treatment and the antimicrobial agent or process are expected to reduce and inhibit the growth of *L. monocytogenes* in the product.
   ii) Sample at least 1 square foot area for each surface, if possible.
   iii) Record the test results.
   iv) If test results are positive for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like or organisms:
      (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.
      (2) In addition, if the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.
      (3) Record the corrective actions taken.
      (4) Retest the food contact surface.
      (5) Repeat corrective action and testing until samples are negative for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like organisms.
      (6) More than 3 consecutive positives should initiate intensified testing, because this shows that the contamination was not eliminated by the corrective actions, and that there might be some other serious problems.

2. Alternative 2 - Use of a post-lethality treatment or an antimicrobial agent or process that limits growth of *L. monocytogenes*.
   i) If a post-lethality treatment is used, conduct tests of food contact surfaces for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms at least quarterly. This recommended frequency is 2 times that for Alternative 1 because in this case, the product only receives one of the interventions.
      (1) Sample at least 1 square foot area for each surface, if possible.
      (2) Record the test results.
      (3) If test results are positive for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like organisms:
         (a) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.
         (b) In addition, if the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.
         (c) Record the corrective actions taken.
         (d) Retest the food contact surface.
         (e) Repeat corrective action and testing until samples are negative for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms.
   ii) If an antimicrobial agent is used, conduct tests of food contact surfaces for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms at least quarterly.
      (1) Sample at least 1 square foot area for each surface, if possible
      (2) Record the test results.
      (3) Each time a FCS test positive for *L. monocytogenes, Listeria* spp. or *Listeria*-like organisms, take corrective action, including intensified cleaning and sanitizing, and retest FCS area.
      (4) In addition, if the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.
      (5) If 3 consecutive tests of food contact surfaces are positive for *Listeria* spp. or *Listeria*-like organisms:
         (a) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.
         (b) Record the corrective actions taken.
         (c) Hold the product.
         (d) Test product for *L. monocytogenes.*
         (e) Retest the food contact surface.
         (f) Repeat corrective action and testing until food contact surface test results are negative for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms.
         (g) If the test results for the product are positive for *L. monocytogenes*,
            (i) Recall the product, if already shipped, and
            (ii) Destroy the product, or

(iii)Re-work the product with a process that is destructive of *L. monocytogenes*.

3. Alternative 3 – Use of sanitation control measures and testing to prevent contamination of product with *L. monocytogenes*.
   i) For establishments that produce non-deli or non-hotdog products, tests for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms should be conducted once a month for large, small or very small volume establishments.
   ii) For establishments producing deli and hotdog products, tests for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms should be conducted at least four times per month per line for large volume establishments, two times per month per line for small volume establishments, and once per month per line for very small (or low) volume establishments.
   FSIS regards production volume as a more important risk factor than establishment's size and intends to use volume as one of the primary triggers for when considering its verification activity. For now, regarding deli meat and hotdog operations, FSIS is considering the break-off between high volume and low volume to be approximately 1.3 million pounds yearly, as derived from the RTE survey.
   iii) Sample at least 1 square foot area for each surface, if possible.
   iv) Record the test results.
   v) If the first test result of a food contact surface is positive for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms, take corrective actions (as specified in the HACCP plan, Sanitation SOP or prerequisite program) and record.
   vi) In addition, if the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.
   vii) Each time a FCS tests positive, take corrective action, including intensified cleaning and sanitizing, and retest FCS area.
   viii) For establishments producing hotdog or deli meat products, if the second test result of a food contact surface is positive for *L. monocytogenes, Listeria* spp., *Listeria*-like organisms, the establishment must:
      (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.
      (2) In addition, if the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.
      (3) Record the corrective actions taken.
      (4) Hold the product (see hold-and-test scenario below).
      (5) Test product for *L. monocytogenes* at a rate that provides a level of statistical confidence that the product is not adulterated.
      (6) Conduct follow-up test of the food contact surface each day until the test result is negative for *Listeria* spp., *Listeria-like* organisms.

(7) At the same time, continue to hold each day's production lot until the test results for the food contact surfaces are negative.
(8) If the test results for the product are positive for *L. monocytogenes*,
  (a) Destroy the product, or
  (b) Re-work the product with a process that is destructive to *L. monocytogenes*.

ix) For establishments producing products other than hotdogs or deli meats, if the third consecutive test of food contact surfaces is positive for *Listeria* spp., or *Listeria-like* organism:
  (a) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include an intensified cleaning and sanitizing.
  (b) In addition, if the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.
  (c) Record the corrective actions taken.
  (d) Hold the product.
  (e) Test product for *L. monocytogenes*.
  (f) Retest the food contact surface.
  (g) Repeat corrective action and testing until food contact surface test results are negative for *L. monocytogenes*, *Listeria* spp., or *Listeria-like* organisms.
  (h) If the test results for the product are positive for *L. monocytogenes*,
    (i) Destroy the product, or
    (ii) Re-work the product with a process that is destructive of *L. monocytogenes*.

For repeated FCS positives, the establishment should also conduct a comprehensive investigation to determine the cause and source of the contamination. At the same time, the establishment should examine and review their HACCP plan, Sanitation SOP or their prerequisite program where the sanitation and testing programs are included, evaluate and see if there is any design or execution flaw, and modify as necessary. The establishment should evaluate the cleaning or sanitizing procedure, the method of determining that the procedures are performed as prescribed, employee hygiene practices, monitoring traffic patterns, equipment design, or change in processing conditions.

In summary, the minimum expected frequency for establishment verification of the effectiveness of their sanitation program by testing of food contact surfaces is as follows:

Alternative 1	2 times /line /year
Alternative 2	4 times/line/year
Alternative 3	
Non-deli, non-hotdog	1 time/line/month
Deli, Hotdog products	
Very Small volume plant	1 time /line/month
Small volume plant	2 times /line/month

Large volume plant 4 times /line/month

FSIS realizes that some establishments' sanitation and testing program may be exceeding the guidance provided above. In this case, FSIS may put the establishment's product into a lower expected frequency for verification testing within the appropriate sampling frame under the following conditions:

a) The establishment addresses major construction within its control program such that the intensity of sanitation and the verification testing procedures are increased during the time of the disruption and for a period of time following the disruption until the data demonstrate that there is no harborage of *L. monocytogenes* or its indicator organisms.

b) The establishment has a good history of proper maintenance of the control program, particularly in regards to such things as the sanitation program, reacting to conditions that might indicate that harborage of *L. monocytogenes* or its indicator organisms is occurring, and appropriately reacting to positive test results for *L. monocytogenes* or indicator organisms.

Examples of establishments' sanitation and testing program exceeding the guidance provided above :

a) The establishment does not have a history of *L. monocytogenes* in either the product or plant environment.

b) The rigor of the sanitation controls and frequency of testing exceed those outlined above, e.g. ,1) the establishment conducts hold and test procedures after the 1st poisitve food contact surface; 2) the establishment confirms for *L. monocytogenes* if the food contact surface tests positive for *Listeria* spp. or *Listeria*-like organism.

B. Guidelines for *Listeria* spp. and *Listeria*-like testing for food contact surfaces and other environmental testing

Listeria spp. or *Listeria-like* organisms are the indicator organisms to be used for *L. monocytogenes* because their presence indicates the potential presence of the pathogen. If these specific indicator organisms test negative, this is indicative that *L. monocytogenes* is not present. Aerobic plate counts (APC), total plate counts (TPC), and coliforms are not appropriate indicator tests for *L. monocytogenes*. Results from these tests do not indicate the presence or absence of the pathogen. However, testing for these organisms can be conducted in addition to the testing for *L. monocytogenes* or its indicator organisms to monitor the effectiveness of the cleaning procedures and level of contamination during processing. FSIS microbiology laboratory methods are available and can be downloaded at http://www.fsis.usda.gov/OPHS/microlab/mlgbook.htm

1. *Listeria* spp. testing

i) The methodology must employ enrichment prior to *Listeria* spp. screening.
ii) *Listeria* spp. screening is conducted from the enrichment using an immunoassay, nucleic acid assay, or equivalent *Listeria* spp.-specific technology.
iii) The above enrichment and screening must be part of a method in use by a government agency (*i.e.*, FSIS or FDA) or validated by a recognized body (*e.g.*, AOAC, AFNOR, ISO, etc.) for the detection of *Listeria* spp. and/or *L. monocytogenes*. Specific validation for environmental sampling is encouraged but not a requirement at this time.

2. Listeria-like organism testing
   i) The methodology must employ enrichment prior to *Listeria-like* organism screening.
   ii) The *Listeria-like* organism positive screening result may be indicated by the presence of suspect *Listeria* spp. colonies after selective plating, or may be indicated by biochemical changes to screening broths (*e.g.*, Fraser Broth) that are consistent with the potential presence of *Listeria* spp.
   iii) The above enrichment and screening must be part of a method in use by a government agency (*i.e.*, FSIS or FDA) or validated by a recognized body (*e.g.*, AOAC, AFNOR, ISO, etc.) for the detection of *Listeria* spp. and/or *L. monocytogenes*. Specific validation for environmental sampling is encouraged but not a requirement at this time.
   iv) Aerobic plate counts, ATP assays and other indicator organism tests that do not specifically meet the above requirements may be employed by the establishment for supplemental sanitation testing. However, these tests do not meet the FSIS expectations for *Listeria* spp. or *Listeria-like* organism food contact and other environmental surface testing programs that may be conducted by the establishment.

C. Hold-and-Test Scenario

Assuming it takes to 3 days to obtain a test result for *Listeria* spp., or *Listeria-like* organisms:

Day 1 – Take food contact surface (FCS) samples

Day 4 –FCS sample (from Day 1) negative for *Listeria* spp. or *Listeria*-like organisms.

- ✓ Continue production as the corrective action appears to resolve problem and test FCS as scheduled.

If FCS sample positive (from Day 1) for *Listeria* spp. or *Listeria-like* organisms.

- ✓ Take Corrective Action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include an intensified cleaning and sanitizing.
- ✓ Test FCS-- target most likely source of contamination, and additional tests in surrounding FCS area

- ✓ Continue production.

Day 7 – Second FCS sample (from Day 4) negative for *Listeria* spp. or *Listeria*-like organisms.

- ✓ Continue production as the corrective action appears to resolve problem and test FCS as scheduled.

If second FCS sample (from Day 4) positive for *Listeria* spp., or *Listeria*-like organisms.

- ✓ Take Corrective Action(as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include an intensified cleaning and sanitizing.
- ✓ Test FCS-- target most likely source of contamination, and take additional tests in surrounding FCS area
- ✓ Hold and test product (for *L. monocytogenes*) for lot implicated in the positive FCS testing.
- ✓ Continue production, hold product from the day's production

Day 8 –

- ✓ Test FCS-- target most likely source of contamination, and take additional tests in surrounding FCS area
- ✓ Hold product from this day's production

Day 9 –

- ✓ Test FCS-- target most likely source of contamination, and take additional tests in surrounding FCS area
- ✓ Hold product from this day's production

Day 10 –

If FCS sample (day 7 sample) is negative for *Listeria* spp., or *Listeria-like* organisms.

- ✓ Continue production and release product from days 7, 8 and 9 production
- ✓ Resume FCS testing according to frequency stated in sanitation program

If FCS sample (day 7 sample) is positive for *Listeria* spp., or *Listeria*-like organisms:

- ✓ Hold product from day 10 production.
- ✓ Test product from days 7, 8, 9, and 10 for *L. monocytogenes*
- ✓ Take corrective action
- ✓ Intensive cleaning and sanitizing
- ✓ Take FCS sample-- target most likely source of contamination, and additional tests in surrounding FCS area

Day 14 – If product is positive for *L. monocytogenes*, destroy product, or rework product with a process that is destructive of *L. monocytogenes*. Recall product if already in commerce.

If the establishment tests FCS samples for *L. monocytogenes,* and the FCS test positive for the pathogen, the sampled lot is considered adulterated.

Every time there is a second or more (consecutive) FCS positive, product is held and tested for *L. monocytogenes*. Only product lots implicated with a second or more consecutive FCS positive are held and tested. Every time there is a product positive for *L. monocytogenes*, product is held, and destroyed or reworked with a listericidal process. Once the FCS testing is negative, implying that the corrective action is working, production is continued.

Repeated FCS positives would imply a critical sanitation problem and the establishment needs to conduct intensive testing and intensive cleaning and sanitizing. At the same time the establishment should investigate the cause and source of the contamination and review the documents where the sanitation and testing programs are included to determine if there are design or execution flaws. The establishment should have provisions in their sanitation and testing program for these kinds of situations.

D. Sentinel Site Program Example

Some establishments have adopted a sentinel site program for the control of *L. monocytogenes* in RTE meat and poultry products. A sentinel site program is similar to traditional Listeria control programs – separate testing programs for the environment and food contact surfaces and increasingly aggressive corrective actions to eliminate Listeria when it is detected. The distinctive characteristic of this control program is that in the case of a positive Listeria test result for a food contact surface area, the sanitation of that particular area will be included in the HACCP plan as a CCP. The CCP is removed when the establishment determines that the food safety hazard has been eliminated and is not reasonably likely to occur.

The CCP is the sanitation program for the particular site and food contact surface sampling as verification of the CCP. If a food contact surface or non-food contact surface tests positive for *Listeria* spp. or *Listeria-like* organisms, testing is intensified in the area of the positive.

If a non-food contact surface sampling site is found to be positive for *Listeria* spp. or *Listeria-like* organisms during routine monitoring, intensified sampling is initiated as soon as possible. Under intensified sampling, three samples per day (one each at pre-op, 1st shift, 2nd shift) are analyzed until a total of nine consecutive samples have been taken and are negative for *Listeria* spp. or *Listeria-like* organisms at that particular site. Swabs are analyzed for each day of production. If a sample finding is positive, testing of that site continues until nine consecutive samples are negative for *Listeria* spp. or *Listeria-like* organisms. Once nine consecutive samples are found negative, that site will be returned to routine sampling.

Similarly, the food contact surface site that initially tests positive for *Listeria* spp. or *Listeria-like* organisms will be placed under intensified testing. If nine consecutive samples under the intensified testing are negative for *Listeria*, that site is returned to routine monitoring. However, if the food contact surface tests positive under the initial intensified sampling, sanitation for that area is designated as a CCP, since *Listeria* cannot

be considered a hazard not reasonably likely to occur. The site testing positive for *Listeria* would be considered a suspect harborage for *L. monocytogenes* and corrective actions taken. Testing becomes the verification step.

Intensified sampling under the CCP requires that 3 samples per day (one each at pre-op, 1st shift, 2nd shift) be taken until nine consecutive samples are negative for **both** *Listeria* spp. and *L. monocytogenes*. If a sample is positive for *Listeria* spp. but negative for *L. monocytogenes*, additional sampling days are added (3 samples per day) until nine consecutive samples are negative for both *Listeria* spp. and *L. monocytogenes*. All products that have contact with that particular site must be placed on hold pending testing results.

If nine consecutive samples are negative for *Listeria* spp. and *L. monocytogenes*, the site can be returned to routine sampling. Product can be released when the line and production date receive negative test results for *L. monocytogenes*. Any sites testing positive for *L. monocytogenes* would require testing of the product.

Sentinel Site Program
Example Flowchart

1. Routine Environmental Sampling
    a. 5 samples/line/week
        i. 3 – food contact surface samples
        ii. 2 – non-food contact surface samples
        iii. *Listeria* spp.
2. Non-food Contact Surface Testing
    a. If negative for *Listeria* spp., continue Routine Environmental Testing
    b. If positive for *Listeria* spp., intensify sampling
        i. Collect 3 samples/site/day for 3 consecutive days for *Listeria* spp. (9 consecutive samples)
        ii. If 9 consecutive samples are negative for *Listeria* spp., return to Routine Environmental Sampling
        iii. If any sample is positive, continue sampling 3 samples/site/day until 9 consecutive samples are negative
3. Food Contact Surface (FCS) Testing
    a. If negative for *Listeria* spp., continue Routine Environmental Testing
    b. If positive for *Listeria* spp., intensify sampling
        i. Collect 3 samples/site/day for 3 consecutive days for *Listeria* spp. (9 consecutive samples)
        ii. If 9 consecutive samples are negative for *Listeria* spp., return to Routine Environmental Sampling
        iii. If any sample is positive, make sanitation for that site a CCP
4. CCP Testing
    a. Collect 3 samples samples/site/day for 3 consecutive days for *Listeria* spp. **and** *L. monocytogenes* (9 consecutive samples)
    b. If 9 consecutive samples are negative for *Listeria* spp. **and** *L. monocytogenes*, return to Routine Environmental Sampling and eliminate the CCP
    c. If a sample is positive for *Listeria* spp. but negative for *L. monocytogenes*
        i. Place product on hold
        ii. Release product if site and production date have negative results for *L. monocytogenes*
        iii. Continue testing until 9 consecutive samples are negative for *Listeria* spp. **and** *L. monocytogenes*, then return to Routine Environmental Sampling and eliminate the CCP
    d. If any sample is positive for *L. monocytogenes*, test the product for *L. monocytogenes*
        i. Reprocess or destroy product testing positive for *L. monocytogenes*

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ATTACHMENT 1

CONTROL REQUIREMENTS for *LISTERIA MONOCYTOGENES* *

Requirements	→ Increasing Risk Levels and Verification Testing →				
	ALTERNATIVE 1	**ALTERNATIVE 2**		**ALTERNATIVE 3**	
	Post-lethality Treatment AND Antimicrobial agent or Process	Post-lethality Treatment OR Antimicrobial agent or Process		Sanitation and Testing Program	
		Post-lethality Treatment	Antimicrobial Agent or Process	Non-deli, Non-hotdog	Deli or hot-dog product
Validate effectiveness of post-lethality treatment	X	X			
Document effectiveness of antimicrobial agent or process	X		X		
Sanitation Program Requirements			X	X	X
Testing food contact surfaces (FCS)			X	X	X
State testing frequency			X	X	X
Identify size and location of sites to be sampled			X	X	X
Explain why testing frequency is sufficient			X	X	X
Identify conditions for Hold-and-Test, when FCS (+)			X	X	X
Additional Sanitation Program Requirements					X
Follow-up testing to verify corrective actions are effective after 1st FCS (+)					X
If follow-up testing yields 2nd FCS (+), hold products that may be contaminated until problem is corrected as shown by FCS (-) in follow-up testing.					X
Hold and test product lots for *L. monocytogenes* using sampling plan that provides statistical confidence. Release, rework or condemn products based on results. Document results and product disposition.					X

OTHER REQUIREMENTS

- Post-lethality treatments must be included in the HACCP plan.
- Antimicrobial agents must be included either in the HACCP plan, Sanitation SOP, or prerequisite program.

- Sanitation programs must be included either in HACCP plan, Sanitation SOP, or prerequisite program. If in the Sanitation SOPs or prerequisite program, there must be supporting documentation for the hazard analysis determination that this hazard is not reasonably likely to occur (NRLTO).
- Verification testing for sanitation in the post-lethality environment may be for *Listeria monocytogenes, Listeria* spp. *or Listeria*-like organisms.
- Product testing must be confirmed for *Listeria monocytogenes.*

- Establishment must maintain sanitation in the post-lethality environment per 9 CFR 416.
- If *L. monocytogenes* controls are in HACCP plan, establishment must validate and verify effectiveness per 9 CFR 417.4
- If *L. monocytogenes* controls are in Sanitation SOPs, their effectiveness must be evaluated per 9 CFR 416.14.
- If *L. monocytogenes* controls are in prerequisite programs, the program and results must be included in documentation required by 9 CFR 417.5
- Establishment must make verification results available to inspection program personnel.

* Patterned after NFPA chart

ATTACHMENT 2

TYPE	CLASS	PROCESSING CATEGORY ISP CODE	REG REQUIRED SAFETY LABELING	WHAT THE HAZARD ANALYSIS/HACCP PLAN MAY ADDRESS
A product containing a meat/poultry product (in whole or in part) which has not received an adequate lethality treatment for pathogens (i.e. raw or partially cooked product).	Not-ready-to-eat	• Raw Product Ground – ISP 03B • Raw Product Not Ground – ISP 03C • Not Heat Treated Shelf Stable – ISP 03E • Heat Treated –shelf stable – ISP 03F • Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H • Products with secondary inhibitors Not Shelf Stable – ISP 03I •	Product must be labeled with statements such as keep refrigerated, keep frozen, or refrigerate leftovers. Use of Safe Handling Instruction (SHI) labeling required.	• Use of SHI labeling (Some establishments may have a CCP for SHI labeling application). If it is not obvious that the product is raw and needs to be cooked: • Features on labeling are conspicuous so that intended user is fully aware tha product must be cooked for safety. This is best conveyed through the produc name (e.g., "Cook and Serve") but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as "needs to be fully cooked," "see cooking instructions," or "cook before eating." • Validation that: a. Cooking and preparation instructions on the product are sufficient to destroy pathogens. b. Instructions are realistic for the intended consumer.
A product containing a meat/poultry component that has received a lethality treatment for pathogens in combination with non-meat/poultry components that need to receive a lethality treatment by the intended user. This includes meals, dinners, and frozen entrees.	Not-ready-to-eat	• Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H	Product must be labeled with statements such as keep refrigerated or frozen. Use of SHI labeling is recommended.	• Validation that: a. The meat/poultry component received an adequate lethality treatment for pathogens. b. Cooking and preparation instructions on the product are sufficient to destroy pathogens. c. Instructions are realistic for the intended consumer. • Features on labeling are conspicuous so that intended user is fully aware tha product must be cooked for safety. This is best conveyed through the produc name (e.g., "Cook and Serve") but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as "needs to be fully cooked," "see cooking instructions," or "cook before eating." • If necessary, hazard analysis should address whether instructions on the labe are needed related to cross-contamination (e.g., avoid contact of contents) a prevention of pathogenic growth (e.g., promptly refrigerate leftovers). NOTE: Inspection program personnel are to collect samples as RTE if the establishment does not follow the guidance above.
A product containing a meat/poultry component that has received a lethality treatment for pathogens that may or may not be in combination with a non-	Ready-	• Not Heat Treated Shelf Stable – ISP 03E • Heat Treated Shelf Stable – ISP 03F	If the product is not shelf stable labeling such as keep refrigerated or frozen	• See part 417 of the meat and poultry regulations.

meat/ poultry component that does not need to receive a lethality treatment by the intended user.	to-eat	• Fully Cooked Not Shelf Stable – ISP 03G • Products with secondary inhibitors Not Shelf Stable – ISP 03I	is required.	

ATTACHMENT 3

Using the ICMSF Sampling Plan

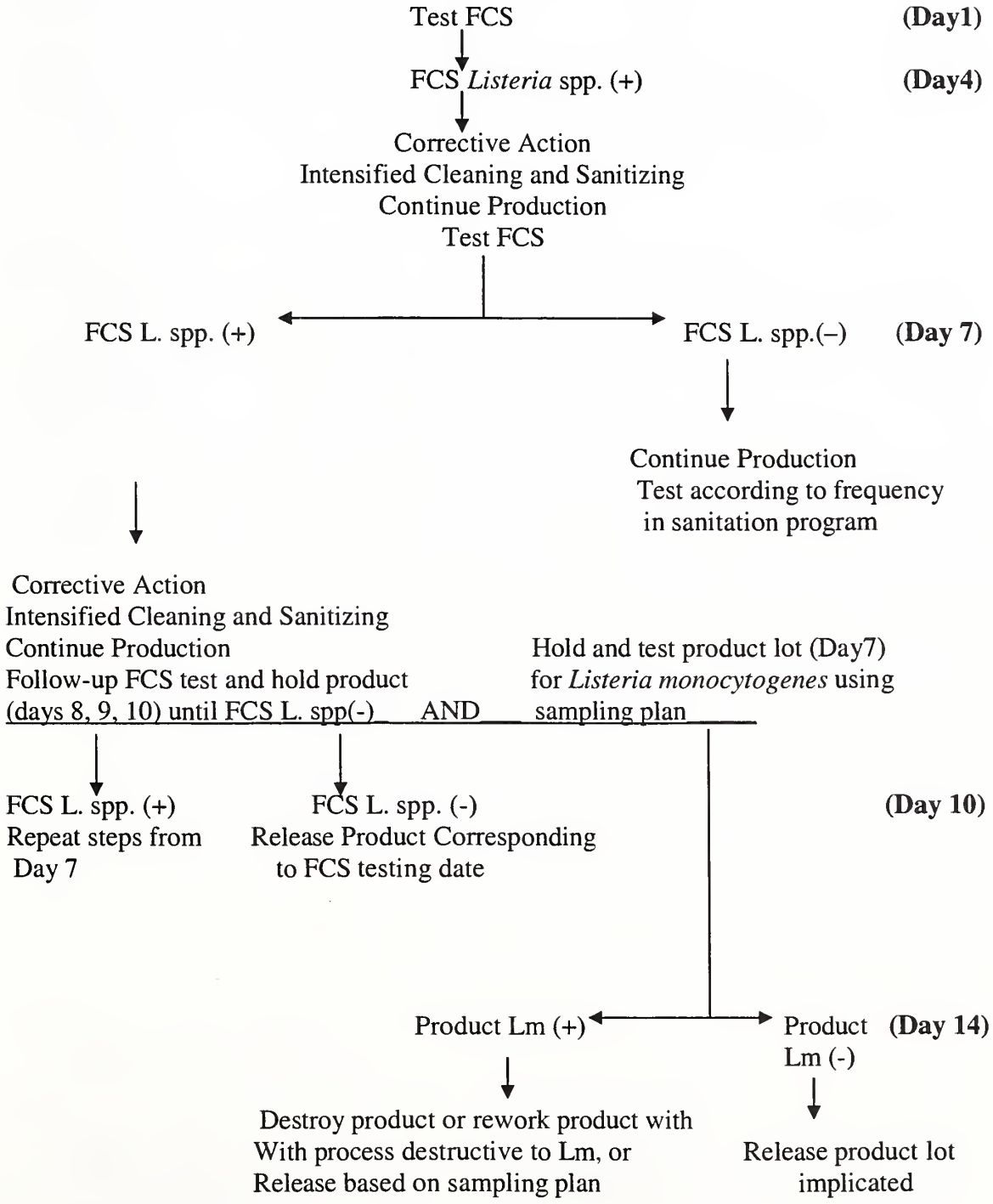
ICMSF classifies 15 different cases of sampling plans, with sampling plan stringency based on degree of risk and the effect on risk of the conditions of use. Case 13, 14, or 15 would apply to the severe category of microbial hazards, including *L. monocytogenes*. In case 13, where conditions of use reduce risk (e.g., food will be fully cooked), the sampling plan is n=15, c=0. (N is the number of samples; C=0 means that none of the "n" samples can be positive for the test organism, in this case *L. monocytogenes*.) For case 14, conditions cause no change in the hazard (e.g., frozen storage), and n=30, c=0. For case 15, conditions may increase the risk (e.g., foods subjected to conditions that allow growth; n=60 and c=0. Note that product samples can be composited.

The following are examples of statistically derived sampling plans that can be used for sampling products under hold-and-test. The number of samples would be as specified for these cases based on the risk of the product. Examples for the categories are included.

Case 13 **n=15, c=0**	**Case 14** **n=30, c=0**	**Case 15** **n=60, c=0**
Frozen products that will be heated and eaten	Products with no growth due to antimicrobial or other formulation considerations such as pH, a_w, etc.	Products that support growth and that will be stored refrigerated
Example: frozen entrees or dinners	Example: hot dogs and deli meats with lactate and diacetate as additives	Example: hot dogs and deli meats that contain no antimicrobials

ATTACHMENT 4

HOLD-AND-TEST SCENARIO FLOWCHART



FCS: food contact surface
L spp.: *Listeria* spp. or *Listeria-like* organisms (test results available after 2 or 3 days)
Lm : *Listeria monocytogenes* (test results available after 6 or 7 days)

The preceding flow chart is a most likely scenario for a hold and test situation. The flowchart illustrates what an establishment could do in case of a positive FCS test, and when a follow-up FCS test is positive. Establishments can design their own procedures or flowchart for their hold and test program. Repeated positive FCS test would imply an inadequate sanitation system or harborage of the pathogen and establishments should investigate and reassess their sanitation program, their equipment layout and design, product flow to determine the cause of the contamination.

Enforcement strategy

Under 9 CFR 430, an establishment with deli and hot dog products in Alternative 3 must provide for testing of food contact surface (FCS). If the FCS tests positive for *L. monocytogenes* or *Listeria* Spp. or *Listeria*-like organisms, the establishment must conduct follow-up testing to verify its corrective actions. If during the follow-up testing another positive FCS occurs, the establishment must hold product lot implicated and test for FCS until the establishment corrects the problem as indicated by the test result. In addition, the establishment must test held product lots for *Listeria monocytogenes* using a sampling plan that will provide a statistical level of confidence. The flowchart above shows a test and hold scenario which an establishment in this type of situation can use. The following section describes the likely action and reaction of inspection personnel during a hold and test situation.

Day 1, 4
The testing program and the test results for food contact and non-food contact surfaces should be available to inspection program personnel. In case of a FCS testing positive for L spp. or *Listeria-like* organism, inspection program personnel will verify that the establishment is performing the corrective actions as specified in the HACCP plan, Sanitation SOP or prerequisite programs, including any intensified cleaning and sanitizing. For deli and hot dog products in Alternative 3, inspection personnel should verify that the establishment is conducting follow-up testing for FCS to determine the effectiveness of the corrective actions, targeting most likely source of contamination and additional tests in surrounding FCS area, and recording all these.

Day 7
Results of the follow-up FCS tests are available on this day. If the FCS tests are negative, then the establishment continues with its normal production and sanitation program procedures. If the follow-up FCS tests are positive for *L. monocytogenes, Listeria* spp. or *Listeria*-like organisms, inspection program personnel should verify that the establishment is following its corrective action for a second FCS positive, including intensified cleaning and sanitizing. For deli and hotdog products in Alternative 3, inspection personnel should verify whether the establishment is holding the product

produced that day and testing the product lot for *L. monocytogenes*. Inspection program personnel should verify whether the establishment is conducting follow-up testing of FCS during each production, and holding all products until a negative follow-up FCS test is obtained. Products produced on days 8, 9 and 10 are held because the follow-up FCS test is available after 3 days. The interim rule states that products must be held until the problem is corrected as indicated by testing. For establishments in Alternative 3 producing deli and hotdog products, inspection personnel can cite the establishment if these procedures are not followed.

Day 10

Inspection program personnel should verify that if the follow-up FCS test is positive, then production lots of deli and hotdog products in Alternative 3 corresponding to this FCS is held and tested for *L. monocytogenes* and that the same procedures are followed as in the second FCS (+) test as in Day 7.

Day 14

For products that test positive for *L. monocytogenes*, inspection personnel should verify that the products are disposed properly, destroyed or reworked with a process destructive to Lm or released based on the sampling plan used, and that the product disposition is recorded accordingly.

Listeria monocytogenes Interim Final Rule

Questions and Answers

Listeria monocytogenes Interim Final Rule
Questions &Answers

Ready-to-Eat versus Not-Ready-to-Eat

1. *The interim final rule only applies to ready-to-eat (RTE) products. Will the provisions in Directive 10.240.3 (Attachment 2) still apply in distinguishing between RTE and not-ready-to-eat (NRTE) product? How will the agency classify products containing both raw and cooked ingredients?*

The provisions of Directive 10,240.3 (specifically attachment 2) dealing with what constitutes a RTE product will still apply after the effective date of the interim rule. A new Directive may replace the existing directive. Under the Directive, products containing both raw and cooked ingredients (e.g., a frozen entrée containing blanched vegetables and fully cooked meat) will not be considered RTE if: (1) the product label prominently indicates the need to cook the products for safety, and (2) there are validated cooking instructions.

2. *Does the agency intend to require all products considered NRTE to bear safe handling instructions in addition to validated cooking instructions (for example, a partially cooked frozen dinner)?*

A safe handling statement would be required if the meat or poultry component is NRTE. If the non-meat component requires cooking for safety, the safe handling statement is not required, but is encouraged.

3. *Are frozen foods to be cooked by the consumer considered to be RTE?*

A frozen product to be cooked may be either RTE or NRTE. FSIS distinguishes between RTE and NRTE foods in Attachment 2 to Directive 10,240.3.

Post –Lethality Treatment

4. *The June 6, 2003 Interim Rule defines a post lethality treatment as "a lethality treatment that is applied or is **effective** after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure." The lethality treatment for dried meat snacks results in a low water activity [<0.85] which is still **effective** after the product is*

packaged and not only suppresses L. monocytogenes growth but can cause L. monocytogenes death. How does FSIS view <0.85 water activity as a post lethality treatment?

Since products with water activity less than 0.85 will not support the growth of *L. monocytogenes* and can sometimes even cause *L. monocytogenes* death, FSIS will consider water activity of <0.85 at the time the product is packed to be a post-lethality treatment if there is a listericidal effect in the specific product and the establishment has provided support documentation to document the intended effect occurs prior to distribution of the product into commerce. The level of pathogen reduction necessary to result in a safe, unadulterated product, based on the expected highest level of post-lethality contamination, also would need to be documented as part of the support documentation. FSIS is identifying criteria that it will tentatively use to assess risk-based verification activity. Generally, if establishments achieve lethality of *L. monocytogenes* such that greater than 2 log reduction occurs, FSIS would view this process as more protective than one providing less lethality.

5. As noted above, many dried meat products not only do not support the growth of L. monocytogenes but L. monocytogenes present on the product will die. If challenge studies are conducted to prove the death of some identified amount of L. monocytogenes, will FSIS consider the products to fall under Alternative I?

When challenge or inoculation studies show death of *L. monocytogenes* during shelf life, those products likely will fall under Alternative 1.

6. FDA has established in the Food Code a definition for foods that are not "potentially hazardous". In the May 1999 "Listeria Guidelines for Industry" [text included in footnote] FSIS quoted the FDA Food Code guidelines for industry to use when assessing the hazards of Listeria. If meat/poultry products meet one or more of the definition criteria, the product is not a*

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* Currently available information indicates that establishments should view a RTE meat or poultry product as a food that supports the growth of *Listeria monocytogenes* unless the 1999 Food Code (DHHS, U. S. Public Health Service, FDA) excludes the product from its definition of a "Potentially hazardous food" (excerpts) because (1) the product has an a_w value of 0.85 or less; (2) the product's pH is 4.6 or below when measured at 24°C (75°F); (3) a food, in an unopened hermetically sealed container, that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution; (4) laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms or the growth of *C. botulinum* can not occur, and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms; or (5) the product does not support the growth of microorganisms..."

potentially hazardous food. How will FSIS use these criteria to determine the appropriate Alternative?

Products that are listed as not "potentially hazardous" in the Food Code definition could qualify in either Alternative 1 or 2. FSIS will look to whether a product has a listericidal effect and whether the growth is suppressed to determine the classification within the appropriate Alternatives outlined in the regulation.

7. Would the use of infrared (IR) technology on slicing logs be considered a post-lethality treatment? If the IR is applied immediately before the slicer, is this close enough to the final product packaging to qualify as a post-lethality treatment?

Although such treatment would assist in controlling any contamination before the slicer, since the slicer itself may become contaminated from a source other than the product, this contamination could be transferred to the product. Hence, this treatment would not meet the intent of Alternative 1 – that the hazard not be present in the package.

Antimicrobial Agent or Process

8. The June 6, 2003 Interim Rule defines an antimicrobial agent as "A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as L. monocytogenes, or that has the effect of suppressing or limiting growth of L. monocytogenes in the product throughout the shelf life of the product." Does FSIS require a specific concentration of inhibitor to qualify as an antimicrobial agent?

There is no "required" percentage. It is up to the establishment to determine which inhibitors to use and at what amount to maintain quality while enhancing safety. However, FSIS is identifying criteria that it will tentatively use to assess risk-based verification activity. Generally, if establishments achieve suppression of *L. monocytogenes* such that 1 log or less growth potentially occurs throughout shelf life, FSIS would view this process as more protective than one allowing greater than 1 log growth.

9. Starter cultures or vinegar, used in product manufacturing or directly in formulations will result in products with a pH <4.6 [creating a product that is not "potentially hazardous" per the FDA Food Code]. How does FSIS view the use of a starter cultures and vinegar as antimicrobial agents?

FSIS will consider starter cultures or vinegar as antimicrobial agents if the addition of the starter culture or vinegar results in a finished product with a pH of <4.6 and this pH level in the specific product suppresses/limits growth.

10. Could cure (156 ppm added nitrite) be considered an antimicrobial agent?

As a general matter, a cure will have an antimicrobial effect in terms of growth suppression. It may even have a listericidal effect; however, an establishment needs to justify any such conclusion as part of its hazard analysis.

11. The June 6, 2003 Interim Rule defines an antimicrobial process as "suppressing or limiting the growth of a microorganism, such as L. monocytogenes, in the product throughout the shelf life of the product." Many dried meat products undergo processes, such as fermentation and/or drying, that create inherent product characteristics [pH<4.6, water activity<0.85] that do not allow growth of L. monocytogenes during shelf life. Will FSIS view the use of fermentation and drying processes as antimicrobial processes?

Fermentation and drying will be considered antimicrobial processes if they result in finished product with pH or water activity that suppresses or limits the growth of *L. monocytogenes*. If this "process" is also listericidal during the shelf life of the product, it could also serve as a post-lethality treatment.

12. On page 18 of the Guidelines (second bullet), FSIS states that "antimicrobials used in the formulation must have an effective antilisterial activity throughout the commercial shelf life of the product." What is meant by this requirement? The preamble to the interim final rule states that the effect of freezing could only continue throughout the shelf life of the product if the product were maintained continuously in the frozen state. Would a frozen product that is thawed under refrigeration just prior to use thus be excluded from the definition of an antimicrobial process?

The requirement that an antimicrobial process or product formulated with an antimicrobial suppress or limit growth throughout the commercial shelf life means that an establishment must have validated that the process or formulation does what is claimed. These validation records must be available to FSIS. The requirement that a product remain frozen throughout its shelf life is intended to exclude situations where a product is distributed frozen and then thawed and sold as a refrigerated product. If the product is thawed as part of the preparation process, the product will be deemed to have been frozen throughout its shelf life.

13. The compliance Guidelines mention the possibility that an antimicrobial process could serve as both a post-lethality treatment and a growth inhibitor. Formulated products that are shelf stable, such as cured ham and pepperoni, are mentioned as examples. Does the Agency have any examples for non-shelf stable products? Are there circumstances under which freezing could serve both as a post-lethality treatment and antimicrobial process, which would allow product to fall under Alternative 1?

At this time, the agency does not have a particular product in mind. The question is whether the processing/formulation of the product is such that it continues to inhibit and reduce/eliminate organisms. If an establishment can demonstrate such an effect through freezing (either through scientific articles or laboratory studies), FSIS would deem freezing as a post-lethality treatment. However, FSIS is identifying criteria that it will tentatively use to assess risk-based verification activity. Generally, if establishments achieve suppression of *L. monocytogenes such that* growth can be more than 2-logs during shelf life, FSIS may not consider this to qualify as a growth inhibitor for Alternative 2. Likewise, if the post-lethality treatment achieves less than 1 log reduction, FSIS may not consider this to qualify as a post-lethality treatment for Alternative 1 or 2.

Validation/Verification

14. Are there specific requirements (e.g., log-reductions) for validating the efficacy of post-lethality treatments, antimicrobial agents, and antimicrobial processes?

FSIS has not established specific requirements. The establishments may select the appropriate levels based on their unique operations and the product's expected shelf life and use. However, FSIS would expect the establishment to have documentation to support its actions and conclusions. Regarding post-lethality treatments, FSIS expects the establishment's HACCP documentation to demonstrate that a post-lethality treatment will be effective in reducing a level of contamination that may occur before packaging. For antimicrobial agents and processes, the Agency expects that there will not be a significant increase in numbers of organisms during the product's shelf life to a level resulting in a public health risk, as well as detectable levels of the pathogen.

15. In Table 1 "Summary of final rule requirements by establishment group," group #2 (68 FR 34229), do items 5 and 6 (validation and verification) apply when freezing is used as the antimicrobial process? (i.e., Is validation of freezing effectiveness required and must an establishment demonstrate effectiveness of freezing in controlling L. monocytogenes on an ongoing basis?)

On the question of validation, pursuant to 9 C.F.R. §§ 417.2 & 417.5 of the HACCP regulations, an establishment must maintain the documentation that supports the decision as to whether a food safety hazard is reasonably likely to occur. Because freezing is a well-recognized bacteriostatic process, an establishment will not have to elaborate extensive scientific justification. As to verification, many establishments include freezing as a CCP for stabilization (cooling of product). The on-going verification of the effectiveness of the CCP can be used to verify the bacteriostatic process. If freezing is not a CCP in a HACCP plan, FSIS would expect the establishment to verify that the product is indeed being frozen below the level which the scientific validation document establish as having the bacteriostatic effect.

16. What records would the agency require for products with formulations that are inherently antilisterial, but that may not be formulated specifically for that purpose but rather to achieve the desired product characteristics (e.g., BBQ and pickled meats, precooked bacon, beef snack sticks)? Would the establishment be required to make changes to the HACCP plan to account for the antilisterial benefit of the formulation/process?

FSIS would expect the establishment to have scientific support to substantiate the antilisterial properties of a product formulation in order to conclude that the nature of the product, as manufactured by the establishment, has such an effect, e.g., citations to published data. As to inclusion in the HACCP plan, that would only be required for a post-lethality treatment (see below). If the post-lethality listericidal effect is based solely on the product characteristics, the agency would expect that the process of achieving the characteristics would be incorporated in the HACCP plan.

HACCP/Sanitation SOP/Pre-requisite Programs

17. In the rule, FSIS states that if an establishment has implemented a post-lethality treatment, it must be included in the HACCP plan. If the establishment has data to demonstrate that L. monocytogenes is not a hazard reasonably likely to occur, must the post-lethality treatment be considered a CCP? Could an establishment include the treatment in a prerequisite program accessible to FSIS via the hazard analysis?

If the establishment can support its determination that *L. monocytogenes* is not reasonably likely to occur, without any reference to the post-lethality treatment, then the establishment would not be required to include such step as a CCP in its HACCP plan. However, FSIS would be interested in the establishment's

justification for having the post-lethality treatment if it is unnecessary for *Listeria* control.

18. What manner of monitoring (when, where and how temperatures are taken) of the post lethality treatment will the Agency find acceptable?

FSIS will not dictate the monitoring and verification requirements for post-lethality treatments. That is the responsibility of the individual establishment.

19. Although the rule allows flexibility in where control measures are written in the food safety system (especially with respect to antimicrobial agents/processes), the rule requires that establishments must have documentation that supports the decision in its hazard analysis that L. monocytogenes is not a hazard that is reasonably likely to occur if it selects to incorporate the control measures in its sanitation SOPs or prerequisite program, rather than in its HACCP plan. What are the evaluation criteria inspection personnel will use in determining if the documentation is sufficient?

FSIS inspection program personnel are simply to determine if the establishment has documentation to support its decision in the hazard analysis that *Listeria monocytogenes* is not a hazard reasonably likely to occur. If *L. monocytogenes* is being controlled by a prerequisite program, inspection program personnel will confirm that the establishment has documented the program. In addition, inspection program personnel will verify that the HACCP plan, hazard analysis, sanitation SOP, and prerequisite programs meet regulatory requirements. If certain questions arise that are beyond their expertise, inspection program personnel generally are directed to contact their front line supervisor and/or the TSC with specific questions. In addition, if warranted, in-plant inspection personnel can also use the expertise, skills, and knowledge of the CSO in determining whether the establishment's control system is in compliance with the regulatory requirements.

20. When measures for addressing L. monocytogenes are included in a prerequisite program other than an SSOP, the establishment must ensure that the program is effective and "does not cause the hazard analysis or the HACCP plan to be inadequate." Likewise, in the compliance guidelines, FSIS indicates that the establishment must verify that the antimicrobial program is effective and "that it does not cause the hazard analysis or the HACCP plan to be inadequate." What does the Agency mean by this?

An effective prerequisite program will reduce the likelihood of occurrence of a hazard. Based on such a program, an establishment could deem a hazard not

reasonably likely to occur in its hazard analyses and need not adopt a CCP for the hazard. However, if the prerequisite program is not effective (or is not being followed), it means the hazard may become reasonably likely to occur. In such a case, the HACCP plan would be inadequate, since it does not include a CCP for the hazard. Accordingly, FSIS expects that establishments will routinely assess the effectiveness of the prerequisite programs and make any necessary adjustments to ensure that *L. monocytogenes* does not become a hazard reasonably likely to occur.

21. What information is needed in the SSOPs to explain how food contact surfaces are kept sanitary and free of L. monocytogenes?

FSIS expects the same degree of detail than that currently included in the establishment's Sanitation SOP, provided that the specific sanitation requirements of the regulation are addressed either in the Sanitation SOP or other specific program regarding *Listeria* control.

Alternatives

22. Can an establishment fall under more than one Alternative?

FSIS recognizes that establishments may be producing products that fall under different Alternative control programs. These various products may best be covered in individual HACCP plans, though an establishment is free to adopt whatever program can best enable compliance.

23. Can there be two Alternatives within a single HACCP plan?

Once again, the decision can be made by the establishment. Products are grouped in a single HACCP plan when the hazards, CCPs, and critical limits are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and observed in practice. Thus, a single HACCP plan could cover hot dogs formulated with and without antimicrobial agents (Alternative 2 and Alternative 3), provided that the HACCP plan clearly distinguishes any critical differences.

24. Some establishments produce multiple types of products on the same line. Will the agency require that the control program, including sampling and test and hold procedures, be the same for all products produced on the line under Alternatives 2 and 3 even though product characteristics differ?

The Alternatives presented in the interim final rule are based on the relative risk posed by various products depending on their characteristics and ordinary preparation practices. If an establishment uses the same food contact surfaces (FCS) on the same production day (clean-up to clean-up) for products falling within two Alternatives, the products would be treated as if they were in the higher risk category with respect to environmental sampling. However, with respect to hold and test procedures, the number of samples tested would be related to product risk (see question # 39) .

25. On the topic of FSIS verification, the Rule states that different options will bring different levels of scrutiny. What about situations in which a plant's production is mixed, i.e. the plant produces cured products with lactate and diacetate, but also produces non-cured products without this anti-microbial agent and would rely solely on sanitation practices for the non-cured product? Assuming that the plant's tonnage is evenly split between the two, how does FSIS structure its scrutiny and verification?

FSIS scrutiny and verification are based primarily on the risk categories of the products. As discussed above, if an establishment produces products falling in two (or three) Alternative control programs, the agency's focus will be on product manufactured under Alternative 3, then 2, then 1.

26. Would frozen RTE products (entrees, chicken nuggets, turkey franks) fall under Alternative 2? What about other products that are processed in a manner that suppress growth?

Frozen products would most likely be classified under Alternative 2. This would be true only if the growth suppression would occur throughout the product shelf life (*e.g.,* not slacked prior to retail sale), otherwise it would likely be an Alternative 3 product. Growth inhibitors such as Aw and pH would likely be used in the Alternative 2 control process, without qualification, if the effect would remain with the product regardless of sales practices. As noted above, it is possible for an establishment to demonstrate a listericidal effect with a specific anti-microbial agent or process. If so, the product could fall under an Alternative 1 control program.

27. Alternative 2 includes products that receive a post-lethality treatment or an antimicrobial agent or process. Does this category include other products that do not support the growth of L. monocytogenes?

Alternative 2 includes all products whose characteristics prevent or limit the growth of *L. monocytogenes* through the shelf life of the product as long as they do not also include a post-lethality treatment that kills *L. monocytogenes* (which would put them under Alternative 1).

Listeria Testing Programs

28. What is meant by "the post-lethality processing environment" and how will sampling and testing of this environment come into play following a positive test result for L. monocytogenes or Listeria spp. on a product contact surface?

The post-lethality processing environment encompasses all areas an exposed product goes through from the end of the lethality step to the time it is packaged. Should a post-lethality processing environment contact surface test positive, the agency would expect that the establishment would investigate the potential source of the positive finding and where that source is located, then take corrective actions to eliminate the source, and verify the effectiveness of the corrective actions. In certain situations, the source of *Listeria* may be the specific equipment that tested positive, such as a slicer. In other situations, such as a positive on a conveyor belt, the source may be a different location than the area tested.

29. The use of the term "indicator organism" throughout the document seems to be in conflict with the definition of "indicator organism" as defined by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). The rule links the "indicator organism" to L. monocytogenes; in this case, is the term "index organism" more appropriate?

The subsequent Directive and related publications will use the appropriate terminology as defined by the NACMCF. However, FSIS does believe that the term "indicator organism" is appropriate because a condition or state of sanitary control is being addressed.

30. The compliance guidance for Listeria spp. testing indicates the methodology must employ enrichment and that screening must be conducted using immunoassay, nucleic acid assay or equivalent Listeria spp. specific technology. Does this mean that cultural methods such as enrichment followed by plating on MOX followed by additional cultural identification steps that stop short of species identification would not be acceptable?

As indicated in the guidelines, any methodology used by a regulatory body or validated by a recognized body is acceptable. Other methods which have been validated or recognized in peer-reviewed articles would be acceptable.

31. The interim final rule requires that an establishment define the size of the sampling site. How does one go about defining a standard size when the equipment to be sampled will vary widely and will likely require differing sample sizes to be most effective?

In determining the sample size for a FCS, the establishment must take into account that the FCS on any individual piece of equipment will vary. For this reason, the establishment written program must provide clear directions on how samples will be taken depending on the available FCS. For example, for equipment with FCS less than 100 square inches, the entire surface will be sampled. For FCS larger than 100 square inches, a contiguous area of at least that size shall be sampled.

32. When sampling plans are required for FCSs, there is a requirement for an "explanation of why the testing frequency is sufficient." What are the criteria surrounding this required "explanation?" Who decides whether the establishment's "explanation" is adequate?

The agency expects that the establishment be able to articulate its thought process as to why it selected a particular frequency. Evidence, such as scientific articles or prior history, could be used, as well as practical considerations such as laboratory capacity, timing and cost/benefit analysis. Should there be an issue involving the "adequacy" of the explanation, inspection program personnel generally are directed to contact their front line supervisor and/or the TSC with specific questions. In addition, if warranted, in-plant inspection personnel can also use the expertise, skills, and knowledge of the CSO in determining whether the establishment's control system is in compliance with the regulatory requirements.

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33. On page 31 of the Guidelines (ii), FSIS states that an establishment should "conduct tests of food contact surfaces for L. monocytogenes, at least quarterly." Was Listeria spp. or Listeria-like organisms accidentally left out, as the absence seems inconsistent with later parts 3 and 3(f) on the same page?

The quoted sentence above should have included reference to *Listeria* spp. and *Listeria*-like organisms.

34. For Alternative 1, FSIS is not requiring establishments to have a testing program for FCS; however, the Agency recommends such testing at least twice a year. What actions would the Agency anticipate taking (e.g., enhanced verification testing) if a plant does not incorporate this testing in its program?

The recommended testing of FCS under Alternative 1 is for periodic verification that the post-lethality treatment is reducing/eliminating post-lethality contamination. Absent that verification, FSIS could request the establishment justify its lack of testing of FCS.

35. For Alternative 1, FSIS suggests that when food contact surfaces are tested and there are 3 consecutive positives, there should be intensified testing. What are Agency expectations regarding the nature of this intensified testing?

FSIS expects that whenever a FCS tests positive for *Listeria* spp., *Listeria*-like organisms, or *L. monocytogenes*, that the establishment would take immediate steps to determine the source of the positive test result, take corrective action, and verify the effectiveness of the corrective action in eliminating the source of the contamination. To accomplish this objective, the sampling and testing regime would likely be more extensive, i.e., "intensive," than whatever occurs on a routine monitoring basis.

36. For Alternative 2, with only a post-lethality treatment, if the retest of the food contact surface is positive, corrective action is repeated until samples are negative – there is no requirement for intensified testing as for Alternative 1, which involves use of both a post-lethality treatment and an antimicrobial agent or process. This would appear to be a less stringent approach than for Alternative 1. Are these examples written as the Agency intended?

For Alternative 1, intensified testing is suggested if there are three consecutive positives. FSIS did not intend for the there to be unlimited testing in the case of Alternative 2 products/processes. FSIS anticipates that, absent an establishment demonstrating a science-based alternative, there be intensified testing after 3 consecutive FCS positives for Alternative 1, 2 consecutive positives for Alternative 2 (and Alternative 3 – non-deli/hot dog) and after one positive for Alternative 3 deli/hot dog.

37. How many samples, which locations, and how frequently should samples be taken as follow-up to show that corrective actions have been effective?

This depends on the specific process and plant, and the location of the positive site that is being "corrected." Sampling frequency is expected to be higher for deli meats and hot dogs in Alternative 3 than for other products.

38. What are the criteria regarding needs for corrective action for Alternatives 1, 2, and 3?

Guidelines for specific criteria for corrective action are described in the FSIS Compliance Guidelines to Control *Listeria monocytogenes* in Post-Lethality Exposed Ready-To-Eat Meat and Poultry Products. Corrective actions are to be followed up by targeted testing to verify that the corrective actions were effective.

39. The interim final rule allows for the release of product placed on hold using a "sampling method and frequency that will provide a level of statistical confidence that assures that each lot is not adulterated." What is meant by a "level of statistical confidence"? Is this ICMSF-based?

FSIS recognizes the limitations of any sampling and testing plan to ensure product safety with 100% confidence. FSIS recognizes that the lower the likelihood of contamination, e.g., <1%, the higher the number of samples required to obtain a high degree (e.g., 95%) of confidence that the pathogen is absent from the sampled lot. Furthermore, FSIS recognizes that statistical sampling is not relevant to environmental sampling and testing, and that repeated sampling and testing of the environment is the best method to determine if corrective actions (e.g., enhanced cleaning and sanitation) have been effective in eliminating potential harborage of any contamination. Although the agency will not dictate any particular sampling plan with regard to lot release following a positive FCS finding, historically, FSIS has recognized the use of ICMSF sampling plans for release of product in the past. Under an ICMSF sampling plan, the number of samples would be dictated by the "case," where Case 13 (n=15, c=0) applies if conditions reduce the hazard (e.g., the product will be cooked or contains an inhibitor that would kill *L. monocytogenes* contamination); Case 14 (n=30, c=0) applies if the conditions cause no change in the hazard (e.g., the product is frozen or shelf stable); and Case 15 (n=60, c=20) applies if conditions may increase the hazard (e.g., the product is refrigerated and supports growth of *L. monocytogenes*).

40. Based on the compliance guidance, it appears that under Alternative 3, hold and test procedures must be conducted for hot dogs and deli meats after a second positive test on a FCS (following an initial positive and corrective action), whereas for other products under this Alternative, hold and test must occur after 3 consecutive positive food contact surface tests. Is this correct?

The interpretation relative to Alternative 3 and hot dogs and deli products is correct, i.e., hold and test procedures must be conducted after a second positive on a FCS. However, for all other products, there is no magic number; rather, the establishment is free to select at what point hold and test will be initiated, provided it can be justified.

41. If an establishment employs hold and test procedures, how would FSIS define the "lot" to be held?

The definition of lot found in the current Directive 10,240.3 would be the appropriate lot for the purposes of hold and test procedures.

42. What Listeria test data must be shared with FSIS personnel?

A description of the *Listeria* Control Program and associated data from monitoring and follow-up sampling are required to show that the program is effective. Any extra sampling data outside of this program may be shared with FSIS personnel at the establishment's option, but is not required. FSIS believes that any decision-making data relative to the production of meat and poultry products is required to be made available to FSIS, particularly if the decision-making documentation impacts the safety of the product. *Listeria* Control Program data must be available for 2 years.

Production Volume

43. FSIS expects establishments to provide production volume and other information on a form that will be electronically available after the rule becomes effective. What are the Agency's expectations as to when this form must be submitted?

The form is currently under review pursuant to the Paperwork Reduction Act and will be available initially only in the traditional paper format. The first electronic format should be available for use sometime in 2004. FSIS will provide establishments with adequate time to provide the information, at least 30 days after FSIS requests information from them.

Labeling Claims

44. Both the preamble to the rule and the compliance Guidelines provide examples of validated claims that would be permitted on product labeling. In

all cases, the labeling claim is for "X added to prevent the growth of L. monocytogenes." Would claims such as "X added to enhance product quality and safety," be permissible?

The Agency will be amenable to any claim that identifies the substance being used, the benefits of the substance, and why it has been used. The claim must be specific, however, to *Listeria* control and it should be limited to safety and not quality attributes. However, FSIS is identifying criteria that it will tentatively use to assess risk-based verification activity. Generally, if establishments achieve suppression of *L. monocytogenes* but growth can be more than 1-log during shelf life, FSIS may not consider this to qualify as a growth inhibitor for a claim.

General

45. How does the agency plan to ensure uniform interpretation of company records, agency policy, and implementation of enforcement actions by FSIS inspection personnel?

As a result of training and supervision, FSIS attempts to achieve uniform interpretation of regulatory requirements. However, because of the scientific basis of the interim final rule, the Directive likely will specify that should the in-plant inspector have any questions as to an establishment's *Listeria* control program, inspection program personnel generally are directed to contact their front line supervisor and/or the TSC with specific questions. In addition, if warranted, in-plant inspection personnel can also use the expertise, skills, and knowledge of the CSO in determining whether the establishment's control system is in compliance with the regulatory requirements.

46. Will Directive 10,240.3, Microbial Sampling of RTE Products for the FSIS Verification Testing Program, be revised in light of the new rule? If so, when?

FSIS plans to issue its revised Directive before the interim final rule becomes effective.